HEALTH CARE DELIVERED BY THE VETERANS' ADMINISTRATION

HEARING

BEFORE THE

SUBCOMMITTEE ON
HOSPITALS AND HEALTH CARE

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

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HEALTH CARE DELIVERED BY THE VETERANS' ADMINISTRATION

Wednesday, September 23, 1987

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:05 a.m., in room 334, Cannon House Office Building, Hon. G.V. Montgomery (chairman of the subcommittee) presiding.

Present: Representatives Montgomery, Penny, Rowland of Georgia, Staggers, Harris, Stenholm, Hammerschmidt, McEwen, Rowland of Connecticut, Smith of New Jersey, and Ridge.

OPENING STATEMENT OF CHAIRMAN MONTGOMERY

Mr. MONTGOMERY. Good morning. The hearing will come to order. Each of the topics this morning is complicated and important. Together they present a diverse set of concerns about the health care delivered by the Veterans' Administration. And, together they say a lot about some of the important issues facing all of American medicine including the VA. The topics are: Medical Inspector General in the VA; and, procreative services.

Originally we had planned also to consider H.R. 2774, a bill introduced by Joe Kennedy which would ensure confidentiality of medical records relating to AIDS. However, at the request of Mr. Kennedy, we will hold our legislative hearing on this bill at a later date in order to receive additional expert testimony.

We will receive testimony on various aspects of a medical inspector including the function, role organizational location and staffing. Nothing can be of higher concern than maintaining both the fact and the perception that the Veteran's Administration delivers consistent, high quality medical care to our veterans. The medical inspector's role can be important and we want to explore all aspects of this serious topic.

We will also receive testimony on H.R. 3161, a bill to authorize procreative services to overcome the effects of a service-connected disability which prevents or impairs the ability to conceive a child. There is hardly another issue that generates more emotion in people than issues involving children and that means their procreation, too.

I often say, and I mean it, that we appreciate the time devoted by the witnesses who come here to help us understand these complex issues. Before we get to their testimony, I want to recognize

my friend and colleague, John Paul Hammerschmidt, for any remarks he may wish to make.

John Paul.

OPENING STATEMENT OF HON. JOHN PAUL HAMMERSCHMIDT

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman.

I'm certainly pleased to be here today to hear testimony concerning the possible establishment of a medical inspector general in the Veteran's Administration and to hear testimony concerning legislation which would authorize the Veteran's Administration to provide procreative benefits to certain veterans.

With respect to the proposal to have a medical inspector general in the VA, several suggestions have been made.

Mr. McEwen, our colleague from Ohio proposes in H.R. 2876 to have a new assistant chief medical director who would be designated as the "medical Inspector general."

Senate Bill 1464, soon to be considered in the other body, provides for a medical inspector general in the Department of Medicine and Surgery and a somewhat similar position in the current Office of Inspector General involved with quality assurance.

Another proposition is that a medical inspector general position be established with the appointee reporting directly to the Administrator of Veteran's Affairs instead of the Chief Medical Director.

A fourth idea is that no medical inspector general is necessary, but that the current medical inspector's office needs to be strengthened.

Mr. Chairman, we need to carefully consider this entire matter to the end that the VA's Department of Medicine and Surgery can better do its job. In any large and complex organization problems are going to occur. They need to be addressed promptly and with vigor and perhaps a medical inspector general of some kind is an answer.

However, I would hope that any proposed solution is not an overreaction to any particular event, such as the recent GAO study on reporting in the VA Medical System or such as the Fort Lauderdale Newspaper reports on surgery in the Miami VA Hospital.

Mr. Chairman, I am sure that our witnesses this morning will provide insight into this matter and that their testimony will be very helpful to us in our deliberations.

Mr. Chairman, I am also pleased that we are having a hearing on H.R. 3161 which would authorize the VA to provide procreative services to certain service connected veterans.

Some time ago the Veterans' Administration General Counsel determined that VA could not now provide these services. Thus the matter comes to the Congress for a possible legislative determination.

Mr. Chairman, I would like to hear from the VA concerning the legal reasoning of the General Counsel. I also look forward to the Chief Medical Director's testimony and that of the Office of Technology Assessment. And, of course, we always look forward to the testimony of the representatives of the major veterans' organizations.

Mr. Chairman, the Paralyzed Veterans of America have given this subject one of its highest priorities. Its testimony today will be of great interest and assistance to all of us on the subcommittee.

And Mr. Chairman, I do have to leave about 5 minutes to 10 'clock, because I have a markup on two bills on the Public Works Committee, so I do leave at that time.

Thank you so much.

Mr. MONTGOMERY. Thank you.

Dr. Rowland of Georgia.

OPENING STATEMENT OF HON. J. ROY ROWLAND

Dr. ROWLAND of Georgia. Thank you, Mr. Chairman. I concur in the remarks that you have made about the importance of the VA and the American Health care of the issues that we will discuss here today.

And I would like to expand on your remarks a bit. The VA not only is a big part of the U.S. health care delivery system, it also presents an opportunity to become a national leader in new methods to deliver care and in new techniques of care itself. Recently, I was in the San Francisco Bay area for a hearing on AIDS, and I came away with a new respect for the magnitude and sophistication of the affiliation between the VA and medical schools in research and patient care both. That kind of alliance puts the VA in front in medical care today.

These alliances also present tough decisions for the Congress and the VA in the form of relatively new issues such as procreative services along with old issues of maintaining quality of care. They certainly have brought us into the forefront of dealing with the terrible epidemic of AIDS and I look forward to future discussion of the confidentiality bill and other related issues.

So, I welcome decisions on these issues because they are the sign of a dynamic and productive organization that the VA is.

Specifically, let me say that I am a cosponsor of H.R. 3161. The role of family and children is integral part of our culture and our society. It certainly seems appropriate to talk about providing help to overcome the service-connected disabilities which prevent veterans from conceiving their children.

In addition, let me say that the issue of quality of care and medical inspection functions have been with us for years and I believe they should remain with us. Constant attention to quality shows that we are never satisfied.

The VA has a particular twist on this issue since Federal funds pay for VA services. That means each citizen and each veteran takes a personal interest in what goes on. And that means we in the Congress and the VA must pay attention to ensuring the perception of the quality of care in addition to ensuring that that quality of care really exists. It seems to me that S. 1464 and the other legislation that we have seen dealing with medical inspectors and quality of care are as much in response to perception as to reality.

And I just want to thank the witnesses, Mr. Chairman, for being here today.

Mr. MONTGOMERY. Thank you.

Dr. Gronvall?

STATEMENT OF DR. JOHN A. GRONVALL, CHIEF MEDICAL DIRECTOR, VETERANS' ADMINISTRATION

Dr. GRONVALL. Thank you very much, Mr. Chairman. We have prepared a full statement and I would ask that it be included in the record of the committee hearing.

Mr. MONTGOMERY. Without objection. You might introduce the other witnesses at the table.

Dr. GRONVALL. Thank you very much. To my far left is Mr. Ralph Ibson from the Office of our General Counsel. Next to him, Dr. Herbert Baganz, who is the Medical Inspector for the Department of Medicine and Surgery. Immediately to my left is Mr. Frank Sato, who is the Inspector General for the Veterans' Administration. On my right is Dr. Howard Cohn, who is Deputy Assistant Chief Medical Director for Clinical Affairs, and to his right, Dr. Susan Mather, who is the Chief of our Pulmonary and Infectious Diseases section in the central office.

Mr. Chairman, we're pleased to be here to make comments on these two important proposals. My opening comment will be brief, but we will then be pleased to elaborate on any of these comments.

First in regard to the proposed legislation that would authorize us to assist veterans or veterans' spouses in attempting to conceive a child, we note that although the bill as proposed does place some limits on the provision of these services, the proposal raises a number of very difficult, both philosophical and practical questions that we think would need to be resolved before it would be practical to provide such services.

In summary, while the desire to have children is an understandable human and humane objective, which we support, we are troubled by many of the unresolved questions and troubled by the prospect of enmeshing the complicated systems of the entire Federal government and through a Federal program becoming involved directly in these sorts of family matters. And those uncertainties led us then, after deliberating on this proposal, to conclude that we could not support the enactment of this legislation. Again, we will be pleased to expand on those views.

In regard to the legislation which is pending in the Senate, having to do with our quality assurance program and our medical inspector program, there are four provisions that are fundamental to that bill. First, to establish by statute an Office of Medical Inspector General in the Office of the Chief Medical Director. In regard to that proposal, we believe that creating such a position by statute with prescribed staffing and with functioning that is structured to be independent from the Chief Medical Director, would be an excessive response to a longstanding issue within the medical profession, namely how best to manage inquiries into professional judgement and medical care issues where treatment outcomes were unfavorable or injurious to the individual patient. We currently do have a Medical Inspector in the Department of Medicine and Surgery. The Medical Inspector does enjoy significant autonomy, and in addition our Medical Inspector's office has excellent cooperation from other physicians in the department. We've recently acted to expand the staffing level of that office, and we believe that the creation of a statutory, independent Medical Inspector General would

unfortunately foster a view that this responsibility is not part of the department's fundamental responsibility in developing and delivering quality care.

In regard to the second part of the proposed legislation, namely that there be an Assistant Chief Medical Director for Quality Assurance, we would comment that the department already has an Office of Quality Assurance. It is headed by a physician director, and once again we do not believe there is a need to dictate by law the precise title and precise qualifications of the office and the individual heading it. We likewise don't believe that there is a need for legislation to direct that employees be periodically instructed about quality assurance, or be disciplined. We already, as a matter of our operating responsibility, do inform our employees about responsibilities for quality assurance. And there have been instances in which we have taken disciplinary action when such matters were necessary. So in our view we currently do have ample authority, both to direct and to discipline DM&S employees.

In regard to the provision in the legislation that would establish a position of Assistant Inspector General for Health Care Quality Assurance in the Office of Inspector General, we oppose this provision for a number of reasons which are developed in our statement. But in summary, I can say that we do have a good working relationship between the Inspector General and the Department of Medicine and Surgery. During the further discussion Mr. Sato can comment directly on that matter, but we believe that the present arrangement fosters an appropriate functioning of our programs and allows appropriate oversight by the Inspector General. The Inspector General at present has full authority to structure his office, appoint or retain both full-time staff and consultants in any area that he chooses in order to carry out his functions. So we do not believe additional legislation is necessary.

In conclusion we view the Senate legislation in this regard as an overreaction promptd in large part by the May, 1987 GAO report having to do with the VA's Patient Injury Control Program. That GAO report pointed out that we had problems in reporting patient care incidents. But the report did not find that quality of care was poor, or that there were problems in regard to quality of care within the department. So although we agreed with the criticisms regarding reporting, we do not believe that the report justifies taking the dramatic steps that are proposed in the Senate legislation and for those reasons we oppose the adoption of the legislation.

Mr. Chairman, this summarizes our position on these two legislative matters. We thank you again for the opportunity to present these in the hearing and we look forward to responding to questions from you and the committee members.

[The prepared statement of Dr. Grovall appears on p. 37.]

Mr. MONTGOMERY. Dr. Gronvall, you oppose both the areas of procreative and also the setting up of an inspector general for medical care?

Dr. GRONVALL. Yes, sir.

Mr. MONTGOMERY. Mr. McEwen does have a bill that authorizes a Assistant Chief of Medical Director of DM&S, and the Chair recognizes him to talk about it since he did introduce H.R. 2876.

OPENING STATEMENT OF HON. BOB MCEWEN

Mr. MCEWEN. Thank you, Mr. Chairman.

And I want to express my appreciation to you for your leadership in holding this hearing on legislation to establish a medical inspector general in the Veterans' Administration and H.R. 3161 which provides benefits for certain disabled veterans.

As you know, Mr. Chairman, we have all heard of the tragic stories about the quality of care provided at our Nation's VA hospitals. Earlier this year the General Accounting Office's report raised questions about the VA's effectiveness and ability to properly report on medical care at some of its facilities.

Also, a Government Operations Committee report raised similar concerns about the level of medical care allegedly provided to some patients at certain hospitals.

And then, Mr. Chairman, there is the tragic situation at the VA Hospital in Cincinnati, Ohio, regarding the alleged murders at that facility and other area hospitals by Donald Harvey. The FBI is continuing its investigation regarding the criminal matter and we are still awaiting the final answers to the questions surrounding this case.

Mr. Chairman, I am distressed that we do not yet have these answers. Stories such as these threaten to do permanent damage to the needed public confidence in the VA Health Care System.

This system is the largest in the world. It's staffed by dedicated professionals who want to serve. And overall the system is very sound. However, it would appear that there are serious problems and deficiencies at the VA which need to be addressed, and oversight systems which need to be improved.

But if we fail to instill the confidence that the VA will provide the proper care to American's veterans, all of our efforts will be for nought.

Veterans and their families need to be assured that we in the Congress stand behind them and will not tolerate poor care or unreported incidents of patient injuries.

It is important that we honor our commitment to ensure that top quality health care is provided for those who serve our Nation.

Mr. Chairman, I believe that the legislation that I have proposed, H.R. 2876, which would establish a medical inspector general at the VA, will improve the VA's ability to concentrate its efforts on the oversight of health care delivery systems at its facilities.

I believe the status quo will not meet the challenges that we face. I also believe that we must seek new solutions to address the rising concerns that many veterans are expressing.

Mr. Chairman, I look forward to working with you and the other members of this subcommittee as we forge an appropriate resolution with the Veterans' Administration.

In reference to H.R. 3161, this of course, is a complex question. Its supporters, particularly the Paralyzed Veterans of America, have given great thought to the matter in terms of their advocacy.

Others have philosophical questions relating to what it is that the mission of the VA should be in this area. I want to study all of their testimony, both medical and philosophical, and I look forward

to receiving their testimony. Thank you, Mr. Chairman, for giving me this opportunity.

Mr. MONTGOMERY. Thank you, very much.

Mr. Hammerschmidt?

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman.

Dr. Gronvall, in your testimony at page 2 you said it was determined over 2 years ago that VA could legally furnish service-connected women veterans with so-called reproductive services only if it could be said that their ability to become pregnant is a disability distinct from the specific physical disability which prevents conception.

Well this is technical and medical, but my question is, what does that mean? When can it be said to be a distinct disability?

Dr. GRONVALL. The matter is a technical one and it's a legal definition. Let me comment on it and Mr. Ibson may want to expand.

Let me draw an example elsewhere where a veteran has a medical problem that leads to reduced vision or blindness. The medical care mission of the department gives us full authority to conduct any medical or surgical therapy directed at the medical problem of the veteran's eyes. The interpretation of our medical services authority, however, would not allow us to provide additional devices which would assist the veteran beyond dealing with the medical disability of the eyes. In that case we have special legislation which gives us that additional authority so we can provide computer assisted devices, artificial reading devices, et cetera, et cetera.

In this case, in regard to reproductive function any medical problem of the individual's reproductive organs can be dealt with by us, medically or surgically, under the authority for providing full medical care. The secondary or derivative function of then having a child or impregnating a spouse, we view as not directly permissable within the medical authority that we have. So that is the basis for the judgement that additional legislation would be necessary to authorize such services since they deal with a secondary matter rather than the medical problem, or the treatment of the medical problem with the reproductive organs directly.

Mr. HAMMERSCHMIDT. Is inability to procreate considered a disability by any American court or by any current law, State or Federal—you may want to answer that for the record. I think we need to make a clear record here and if you want to answer it now, why fine.

Dr. GRONVALL. Mr. Ibson, could you answer that question?

Mr. IBSON. I don't know that it is Mr. Hammerschmidt, but in any case we are limited by a definition in Title 38, which is perhaps a narrower definition of disability than in other arenas. And that definition is, "a disease, injury or other physical or mental defect." So that the terms of the question Dr. Gronvall was answering, and for purposes of an analysis of in vitro fertilization we might find, for example, that a woman with damaged fallopian tubes has such a physical disability. We could provide treatment for that disability. But the inability to become pregnant itself is a disability, we would not be able to provide services to overcome it. We could do so if the authority were broader, as provided in for in H.R. 3161, for example, where the terminology is to overcome a disability.

Mr. HAMMERSCHMIDT. I thank you.

Now let me shift over to the other bill for a moment. I'll just have one more question. What is the current staffing in the Medical Inspector's Office and how much is it being augmented?

Dr. GRONVALL. Let me ask Dr. Baganz to comment on that. He heads the office.

Dr. BAGANZ. Mr. Hammerschmidt, currently we have four employees. We've been authorized to recruit for two additional. Two additional people have been identified off a certificate, short of some technical personnel actions hopefully happening in the next few days. Two nurses with advanced degrees and experience in the area that we function, we hope to have on board very shortly. So that will give us a staff of six.

Dr. GRONVALL. I would only comment, Mr. Hammerschmidt, that that number indicates the defined number of people specifically in the central office in the Medical Inspector's Office, but it is not an indication of the total amount or number of personnel involved in the medical inspector investigations, since we utilize people from our medical centers to conduct many of the investigations.

Dr. Baganz, you might give some quantitation of that.

Dr. BAGANZ. My office is an active office with a great deal of information that flows from the field through it, and we do function under some pressure with the current staffing, but have, I believe, been able to meet the work load because of the cooperative arrangements we have had with field staff and with all the components within central office. Components including the Office of General Counsel, as well as the Department of Medicine and Surgery. The Regional Director's Office is the line arm of the Chief Medical Director, likewise provides us a great deal of staffing to assist in the investigations and analysis.

In the field we readily use all of the staff in the medical centers and work with the chiefs of staff and directors, particularly, so that although the staff is small we do invoke the entire employment of the Department of Medicine and Surgery with some ancillary help so that we do have a large participation in the quality assurance investigations that are involved in my office.

Mr. HAMMERSCHMIDT. I thank you for your response.

Thank you, also Dr. Gronvall.

Dr. GRONVALL. Thank you.

Mr. MONTGOMERY. Thank you.

Dr. Rowland?

Dr. ROWLAND of Georgia. Thank you.

I want to follow up on the question that was asked by Mr. Hammerschmidt. You say that—and you used the example, scarring of fallopian tubes and you would proceed to try to restore patency to the fallopian tubes within the jurisdiction that you have.

But let me ask you this question. How would you know whether or not you were successful if you did not undertake fertilization of an ovum after what you had done had been completed?

Dr. GRONVALL. I think that there is the ultimate test not only of the patency of the fallopian tube, but functionality, would be that it successfully transmitted an egg from the ovary to the uterus and the person became pregnant. So in the context of your question, that's the ultimate test of function, surely of the fallopian tube.

Dr. ROWLAND of Georgia. Well, then how would you make that determination? You say that is beyond what you would do now in procreative services. How would you do that? Would you refer the patient outside the VA to get that done? It seems to me it would be relatively simple for you to go ahead and complete the procedure to the bottom line.

Dr. GRONVALL. Again, I'll ask Dr. Susan Mather to expand my comment, but basically within the present authority that the department has, we direct our medical or surgical care or intervention to the particular medical problem that's involved but we stop short of the additional steps in providing in vitro fertilization or other services.

Dr. ROWLAND of Georgia. So you really don't know whether what you've done was successful or not, do you?

Dr. GRONVALL. Dr. Mather, can you comment?

Dr. MATHER. I think that we have not really done this in very many cases, but it would be referred out and then the surgeon who did the surgery could, and probably would, use air studies to determine patency. Although he might even advise against surgery since there is some evidence, I believe, that this kind of surgery tends to contribute to tubal pregnancy. And it is not considered very successful surgery in that context.

And I think it's rather been overcome by in vitro fertilization procedures.

Dr. ROWLAND of Georgia. Let's talk about the male and repair of the vas, or whatever in the case of an injury, and whether or not that person is going to be fertile after a repair has taken place. Again you would not follow that any further than just to do the repair?

Dr. GRONVALL. Dr. Cohn?

Dr. COHN. Well, I think that that's substantially true. I think if you did the repair, and we do any number of repairs and have some statistics on that. Just briefly we've definitely done more in Fiscal Year 1986, for example, than Fiscal Year 1985. Now admittedly not all of those repairs are directly done with regard to infertility, but one could certainly do, and I think sperm counts assessment and motility would and should be done post those procedures. Beyond that, as you've heard, we would not be really authorized to go much further.

We'd certainly counsel the veteran. We certainly do do that. And perhaps recommend certain other rehabilitative approaches.

Dr. GRONVALL. I think, if I may, the example you used here is a good one to clarify where we interpret the line of our current authority. In regard to a male veteran with injured reproductive organs we could utilize medical, or in this case, surgical therapy to reconstruct or repair the vas deferens. We could assess whether that was successful by comparing the presence of sperm in the ejaculate before and after surgery and so we would provide surgical care directed at the medical problem that the veteran has. But if that were done and we found that there were spermatozoa, motile sperm in the ejaculate following that repair, but the couple still did not get pregnant, the veteran spouse did not get pregnant, our interpretation of our current authority is that it stops short of providing the additional insemination of the veteran spouse using a

sperm sample. And that is not a medical or surgical therapy directed at the medical disability that the veteran has.

And again, that's the basis of our saying that it would require additional legislation to do that. And the present legislation, of course, proposes that.

Dr. ROWLAND of Georgia. But I believe that you don't support the present legislation to do that, is that correct?

Dr. GRONVALL. Correct.

Dr. ROWLAND of Georgia. Well, let me ask you this.

Mr. Chairman, my time is out, but let me follow up on this question.

You, as a medical man, Dr. Gronvall, Dr. Cohn, wouldn't you like to have the prerogative to follow up on this yourself rather than to refer to someone else to make a determination about what you had done was successful? I just wonder, are you concerned about the expense of this? Is OMB having some influence on the stand that you're taking here?

Dr. GRONVALL. I would say not really. I think in either of those cases, the relative number of people involved, veteran patients involved, is relatively modest and expense is, of course, always a question. But the primary factors that have led the department to say we can't support the legislation at this time, I think are the kinds of questions that we've raised in our full statement: How many times would it be appropriate for us to provide artificial insemination therapy? If a couple has one child is that adequate? Should it be two, three? Is there a limit? The question of the case where a veteran had known problems with drug abuse or other problems, would put us inevitably in the position of trying to develop judgments about the suitability of people to become parents. And I think that the more of those kind of issues we deliberated on within the department, among the physicians within the department, the more anxiety was expressed about the inability of the Federal government to become a participant in dealing with all of those questions which we view as properly the prerogative of the individual person and the individual family. And so we became, I think, quite concerned that a complex Federal apparatus and machinery with rules, regulations and criteria would become enmeshed in family matters for which we don't feel we see adequate answers in the near future.

So it's a complicated matter. As I said in my opening statement, I think all of us within the department as medical professionals view childbearing as highly desirable. It is a very understandable and highly desirable human and humane response. And in the case of the injured veteran where the injury prevents childbearing, we feel a very strong responsibility to utilize whatever medical and surgical therapy we can to try to correct that medical problem, but to take the additional steps that are proposed, we feel raises a number of troubling issues for a Federal program that we don't see easy or very workable answers to. It's a real dilemma situation.

Dr. ROWLAND of Georgia. I understand the dilemma and I certainly appreciate what you've said. However, it seems to me that the disability, that is not being able to conceive as a result of some service-connected problem that the VA ought to be out front in trying to deal with that in every aspect of it.

Thank you, Mr. Chairman.

Mr. MONTGOMERY. Thank you, Dr. Rowland.

The Chair will take the members the way they came in after we started the committee hearing.

Claude Harris of Alabama?

Mr. HARRIS. Thank you, Mr. Chairman.

I'd like to direct a question to Mr. Sato. As a new member of this committee, I'm not familiar with the procedures of your office and I would like and appreciate it if you would just explain to me the procedure that you would take regarding a complaint by a veteran for inadequate medical service?

Mr. SATO. Generally a complaint like that, sir, would be handled through our complaint center and if it was a quality of care issue we would refer it directly to Dr. Baganz, the Medical Inspector.

When the results come back and if whatever the complaint happens to be, we feel that it may not be responsive or satisfactory we may pursue it further back through the Department of Medicine and Surgery, or we may follow up on it ourselves to assure that the complaint is appropriately addressed in a timely way. That's our normal process.

Mr. HARRIS. Well, I understand that the Office of Medical Inspector established in 1980 comes within the Department of Medicine and Surgery. Let me ask you this.

Do you see a conflict that this inspector is reporting directly to the Department of Medicine and Surgery?

Mr. SATO. No, sir, I don't. I think that when we're talking about quality of care issues, certainly the Medical Inspector is autonomous from the medical center itself that might be involved. And if there is a concern about a conflict, we may get directly involved ourselves, and we have in certain cases.

Mr. HARRIS. Well how do you feel that this inspector could maintain his integrity when he must first report to the Department of Medicine and Surgery?

Mr. SATO. Well those are types of issues, sir, that, as I mentioned earlier, if we feel there might be a perception or in fact a potential conflict because of the way his office is set up, we would handle the particular issue directly. But most of the complaint-type cases aren't involved in that type of a situation.

Dr. GRONVALL. Mr. Harris, if I may just add a comment to that.

Mr. HARRIS. Yes, sir.

Dr. GRONVALL. As Chief Medical Director the law holds me specifically accountable for delivering quality of care to veterans. As a physician/administrator I view my fundamental responsibility to be that of administering a system that delivers quality of care to veterans. If there is an allegation made within one of our hospitals by a veteran or a staff member that quality care was not delivered, I ask people who work for me, in this case the Medical Inspector, to investigate. If they find that there was a problem or that it was inadequate or that someone is not competent to deliver quality of care, we take action on that.

The record is that we have dismissed a number of professionals, and we regularly do that every year. We've taken steps to remove clinical privileges from individuals that we find are not capable of quality of care. We've investigated whole programs and made deci-

sions that certain medical centers should no longer deliver certain kinds of care. Open heart surgery was an example of that within the past several years. So I see no inherent conflict in the fact that professional individuals who report to me investigate quality of care matters within the department. In fact, I see that as a very important part of my responsibility in carrying out my job. In every case the investigations of the Medical Inspector are reviewed by the Agency Inspector General Office, so Mr. Sato's office remains in an oversight position to review all of the inspections we undertake within the department.

Mr. HARRIS. I understand that.

But what concerns me, Doctor, is it's hard to investigate yourself. I mean we see situations like in the Justice Department where an allegation comes up, we've got special prosecutors, and I think of any number of situations where outside people are asked to investigate a complaint. It just appears to me that it would certainly as far as—and I know in your statement you said that the assurance program was not a claim fixing process.

It certainly appears that—and I know a concern of the veterans is that the medical professionals that are at fault not fail again. And I'm just not sure that the current process described to me is sufficient to weed out and identify repeat offenders of good medical practice.

Dr. GRONVALL. Just a brief comment, if I may. We have an extraordinary amount of external review and scrutiny in our medical program. By that I mean, a host of agencies external to the VA are involved in peer review of the quality of our medical care programs; the Joint Commission on Accreditation, Residency Review Committees, et cetera, et cetera. I could supply a list of some I think 50, or 60, or 70 such review bodies external to the VA.

I agree totally with you that we need and in fact we invite such external scrutiny, and often when there is a difficult judgement call to be made our typical approach is to convene panels of experts from outside the VA to assist us in bringing that kind of independent judgement to bear. So that's a regular practice that we engage in.

Mr. HARRIS. Thank you, Mr. Chairman.

Mr. SATO. Excuse me, sir.

Mr. MONTGOMERY. Thanks a lot.

Go ahead, Mr. Sato.

Mr. SATO. I want to just add a comment, Mr. Harris, on top of Dr. Gronvall's remarks. We do routinely review all of the investigations performed by the Medical Inspector. And for example, since the beginning of the fiscal year, we have performed reviews of 245 such cases. We have returned 26 of those because there were certain questions that we felt needed to be answered. Now over and above that, as I mentioned earlier, if any case would raise some questions on our part, we may go onsite ourselves, as we have in certain cases.

So the conflict situation I don't believe has been a major problem that I'm aware of.

Thank you, sir.

Mr. MONTGOMERY. Thank you.

Let the record show that Mr. Stenholm of Texas was here. He had to go to another meeting.

Chris Smith of New Jersey.

OPENING STATEMENT OF HON. CHRIS SMITH

Mr. SMITH of New Jersey. Thank you, Mr. Chairman, and Dr. Gronvall and members of the VA. Welcome to the committee.

First of all, I want to say that I have a great deal of sympathy for the intent of H.R. 3161. I've had two very close friends who have tried desperately to conceive a child. In both cases they were unable after herculean efforts to do so, they have both subsequently adopted children, but they continue to try. And knowing of their pain and of the pain of so many people who have tried to conceive children and to have a family, makes me at least on the surface sympathetic to the goals of the legislation.

However, as you point out, Doctor, there are some very substantive problems with the legislation as offered and as standing before this committee, not the least of which is that it could substantially change the mission, the health care mission of the VA. But I think the larger question that this committee will be looking at, the larger ethical and moral question has to do with the ethicacy of such things as in vitro fertilization, test tube babies. I think it's far from a settled question, as at least some of the testimony provided by the PVA would suggest. I know that I have serious concerns about the disposition of children so conceived. What happens if it is found that those children are suffering some abnormality, such as Down Syndrome, sometime down the line or they therefore were thus candidates for abortion? What is the legal implications to the VA for having been part of that process in terms of lawsuits, malpractice? I think there's a whole host of problems that could stem from the passage of the legislation, especially with inclusion of the in vitro portion.

I would point out, as pointed out by the PVA, that the DOD does provide for fertility services, but explicitly, if their information is correct and I have every reason to believe it is, excludes in vitro fertilization. I would appreciate it, Doctor, if you could expound upon some of the misgivings that the VA has concerning specifically in vitro fertilization and generally the thrust of H.R. 3161.

[The prepared statement of Congressman Smith appears on p. 35.]

Dr. GRONVALL. Let me make a very brief comment, Mr. Smith, and then invite Dr. Cohn and Dr. Mather to add to it.

You have listed a number of the very thorny issues that we deliberated on. I again would like to assure you and the committee that our position on this legislation was not a simple one based just on the fact that it would cost some extra money and might be difficult to administer. It was the result of agonizing deliberation primarily by medical professionals on the kind of questions that you raised and our feeling that, as I said, enmeshing the full weight of the Federal government now into those very difficult questions would get us quickly beyond answers that we felt were available at the moment.

Dr. Cohn, Dr. Mather, you might expand.

Dr. COHN. Well, I just wanted to say that following up on some earlier comments I made, the VA performed in males—in Fiscal Year 1985 1,468 devices were so placed in 98 medical centers. That number increased to 1,614 in Fiscal Year 1986. So it would leave you with the impression, indeed, that there is a considerable amount of work that goes on. The follow-through, of course, in terms of Congressman Rowland's previous question still remains at issue perhaps.

In females we carried out seven surgical procedures, including two wedge resections of ovaries and repairs of fallopian tubes, et cetera, no artificial inseminations. So there are procedures that are done.

Perhaps I'll turn it over to Dr. Mather.

Dr. MATHER. I think probably the philosophical questions are at the heart of the VA's difficulty with the bill and with procedure. While in this country pregnancy and delivery is a medical experience largely, although there are people who take exception to that. Conception is not, in most situations and I think one that is very difficult to get into, because people of most faiths disagree on the ethics of the various procedures. I think there are people who disagree with technical interventions in conception and others who feel that this is a part where physicians or scientists are helping God's mission in the world. So I think people of good faith can disagree on that. And that's one of the areas that I think the Veterans' Administration is a little reluctant to make decisions that previously have been left up to perhaps a higher being.

And one of those decisions is the criteria for fatherhood or motherhood. Is a person with a history of abusive behavior; is a person infected with the AIDS virus automatically entitled to an attempt to become a parent? These are very thorny questions and I think questions that we'd all agree that people of good faith could disagree on. And we're a little reluctant to dive in where maybe angels haven't feared to tread, but certainly human beings have.

Dr. GRONVALL. And I might just pick a specific example. The instance of a veteran and spouse where we had medical information that led to a very strong conclusion that children would be mentally retarded. We, if the veteran has a medical problem with reproductive organs, we feel that it's appropriate to engage in medical or surgical therapy. But if the issue then is to go beyond that to ensure the birth of a child, I think that becomes a difficult problem for us. All of the actions that we take properly need to be publicly accountable. We need to have standards and criteria. And the vision of developing appropriate standards about mental capacity of potential children or the mental capacity of parents to care for them, let us say one artificial insemination results in a retarded child, what do we do about the second request by the veteran or the spouse? And the words eugenics and government control of the future population of the country quickly get into that kind of discussion. And again it's for all of those reasons that we backed away from this, while as I say, absolutely and strongly believing that child birth and having children is one of the most natural and highest goals and objectives of husband and wife, we felt that we did not see a way that as a government program we could easily become enmeshed in those issues.

Mr. SMITH of New Jersey. Thank you very much, Doctor. I see my time is out.

Mr. MONTGOMERY. Tim Penny of Minnesota.

Mr. PENNY. Thank you, Mr. Chairman.

I want to talk about quality assurance a little bit. If the changes that have been proposed are adopted, is it your view that they would then replace all existing mechanisms, and if not how would you envision them meshing with the existing structure for quality assurance?

Dr. GRONVALL. I haven't thought that question through because it hasn't been posed exactly that way. I would surely not see this as replacing everything we're doing. If the Senate bill were adopted as it now stands, an office would be structured in the Inspector General's Office. I'm assuming that would become the part of the Inspector General's Office that conducted the oversight reviews of all quality assurance matters. That's now being done by staff in the Inspector General's Office. Similarly, within the Department of Medicine and Surgery it would require new titles for people and offices, some reorganization of our structure. It would mandate specific staffing and so we'd have to re-adjust staffing. But to that extent I think we would attempt to move smoothly from the existing staffing and function into the mandated structure that the bill contains.

Mr. PENNY. Is it your judgement that there would be little if any affective change in quality assurance even with the addition of these new personnel and review authorities?

Dr. GRONVALL. Yes, sir. And in some of the opening statements given today by committee members there were references to a number of tragic events that had occurred. I would not minimize the tragedy of those events. We've had previous hearings in which we have described incidents of tragic malpractice and tragic errors that have been made by our staff. And so I wouldn't minimize those, but I am certainly convinced that this statutory change would not mean that a year from now none of those kind of incidents or tragedies or untoward outcomes would occur. And it is my professional judgement that the change envisioned in this legislation by structuring quality assurance into a more legalistic and policing kind of approach would in fact reduce or interfere with efforts to accomplish peer accountability and constructive change whenever a problem has been identified that has led to less than desirable care.

Mr. PENNY. Mr. Chairman, I don't have any further questions. Thank you, Dr. Gronvall.

Mr. MONTGOMERY. Thank you, Tim.

John Rowland from Connecticut.

Mr. ROWLAND of Connecticut. Thank you very much, Mr. Chairman.

Doctor, I wanted to follow up with regard to your comments on the medical inspector general. You indicated in your testimony and also in responses to questions that you would oppose a separate position for the Medical IG's post in that you think the process as it now exists takes care of any particular problems that may come up.

Would you tell, and I believe Medical Inspector is the terminology of the person in charge now?

Dr. GRONVALL. Correct.

Mr. ROWLAND of Connecticut. Who hires that person and who does that person report to?

Dr. GRONVALL. The decision on the appointment of a Medical Inspector is made by me. I believe the position is one for which the Administrator has ultimate approval authority but the individual is selected by me. The individual, in this case Dr. Baganz the current incumbent, reports to the Deputy Chief Medical Director, which is a part of the office of the Chief Medical Director. So in that sense he reports to me.

Mr. ROWLAND of Connecticut. You also mentioned that the IG's position would be, just to quote you, and you can correct me if I'm wrong, "excessive response and would burden rather than enhance your efforts and the efforts of the VA." And you also mentioned that you stand ready to have outside panels and there had been outside panels and independent reviews of particular cases.

Now let me play the devil's advocate for a moment. If you're willing to have outside panels in independent analysis, why would you then be opposed to the IG's position which really would almost do the same thing?

Dr. GRONVALL. I'd be glad to respond to that.

I view the Veterans' Administration as seeking to deliver care that meets the standard of quality that exists throughout the medical profession in America today, whether that's in a university hospital, or a community hospital, or a VA hospital. Therefore, when we have a problem we often turn to panels of medical experts from outside the VA who represent academic institutions or the practicing community and we view those as medical peers who can bring outside expert medical judgement.

I do not view the Inspector General as having a medical expert function. The Inspector General of the VA, like the Inspector General in each of the Federal agencies, was established as an audit function to review instances of fraud, waste and abuse. And I do not view the Inspector General as the place to establish professional medical judgement that I would want to turn to for peer review of the quality of medical care. I think the Inspector General is just a very different kind of function. So I have no problem with external medical, professional judgement and we seek that regularly. But I don't believe that that characterizes the kind of judgement that we get from the Inspector General Office.

Mr. ROWLAND of Connecticut. When there's a so-called problem, and I hate to use that term, but when there's a so-called problem, how often is the peer review, independent counsel used? And I believe someone threw the numbers out earlier. Is it a great percentage of the time? Is it just in specific cases?

Dr. GRONVALL. It's hard for me to give a quantitative answer to that, because I tend to be familiar with the most difficult cases that we have that haven't gotten resolved at a lower level. And quite characteristically when we have a really difficult case, the way we handle it is by convening a panel of people from outside the VA and ask them to make an onsite inspection in the particu-

lar medical center and then we rely on the judgement of those totally external medical experts.

Again, I can't give a quantitation to that, but the ultimate point of a difficult medical judgement that we've been unable to resolve easily within the department, in almost every case tends to be turning externally for that kind of judgement. And so we regularly have blue ribbon panels, expert panels, people from outside the VA.

Mr. ROWLAND of Connecticut. Does anybody else want to comment on that?

Dr. GRONVALL. Maybe Dr. Baganz could give some kind of quantitation.

Mr. ROWLAND of Connecticut. Basically I want to know is it once in a while, or is it done quite often in trying to rectify problems that may come up?

Dr. BAGANZ. Well basically the profession of medicine and its practice, peer review is not new and it goes back through the ancient times. But it's what really is the foundation of quality of care. That's not new in the last several years. So that peer review is an integral part of the profession.

We attempt to have that as objective as possible , without conflicts of interest. The complexity of answering the question is that the VA is so interspersed and intermixed with academic medicine with a high percentage of our physicians working part-time at university hospitals and medical schools, that the distinction between a VA physician and a non-VA physician in peer review in our medical centers gets very fuzzy. We do not believe we work by standards different than those of medical school or university teaching hospitals. These people are involved in the care of our patients and they are obligated to participate on a daily basis in our quality assurance programs. And we use those people in investigations. So the distinction between internal and external gets fuzzy when you're talking peer review because of the high integration we have with the majority of the medical schools of this country, with most of our hospitals being integrated or affiliated with them.

Mr. ROWLAND of Connecticut. Thank you very much.

Mr. PENNY [Presiding]. Next, Mr. Ridge?

Mr. RIDGE. No questions.

Mr. PENNY. Then Mr. McEwen?

Mr. MCEWEN. Thank you, Mr. Chairman.

I guess other than the fact that I caught that you were basically opposed to the Senate bill, I have difficultly conceptualizing in my mind specifically what it is about it that causes you concern.

Dr. GRONVALL. If I had to give a single sentence, I would say that we view it as unnecessary and enacting by statute to a fair extent, matters that already are within the authority both of the Chief Medical Director and the Inspector General, so it by statute structures elaborately defined mechanisms to carry out authority that already exists and in our view is being adequately carried out.

Mr. MCEWEN. What is the Inspector General's Office doing in the Harvey cases, incidentally?

Mr. SATO. Mr. McEwen, we are involved in an oversight role in that case. Currently it's really a part of the Chief of Police Wilson case, which is sitting before the Office of Special Counsel in OPM.

Until their report is completed and received by my office, we have suspended any further work and that's in accordance with the way the process is set up.

Mr. MCEWEN. I guess really we're not doing anything at this point?

Mr. SATO. No, sir.

And in fact, as you know, the Harvey case is before the courts as I understand it.

Mr. MCEWEN. Do you feel you have an adequate staff to continue, a proper budget to handle these kinds of things?

Mr. SATO. Well, that's a difficult question for me to answer. I think I've made a case with the Administrator and with the Office of Management and Budget. I do feel that on a comparative basis the Office of the Inspector General in the Veterans' Administration is not appropriately staffed. But I think that in today's economic situation and with the budget constraints, we of course are doing the best we can. I think that in the area of quality assurance we have done substantial work, both in terms of our regularly scheduled audits of medical centers, as well as our special reviews such as in the area of licensure, which I'm sure you're familiar with.

Mr. MCEWEN. Well, you understand our dilemma. We want to help you and the only way that we can help you is to augment your position, or strengthen the position somewhat. You say you don't need help and the only way that we can point out that you do need help is to say, you're not doing a very good job. And we don't like to say that. So therefore, here we are tiptoeing around; you're doing the best you can but we don't quite think it's fully adequate. We think you need a little help. But when you say, "I don't need any help", then we say well then why didn't you do this, that and the other thing. We don't feel comfortable in that relationship because we know how hard you're working.

If you've got a solution for that, I'm open. You just think you're doing fine.

Let me just tell you about Cincinnati. Cincinnati has goné on for years, and years, and years. I've sent letters and I've tried to talk to the Director and I've sent American Legion teams down. I've sent VFW teams down. They've been very cooperative, and they've looked into individual cases. But it just goes on, and on, and on. It just seems like there ought to be a better way. Oversight of 172 hospital by four people is difficult. We have complaints such as veterans that were taken down there have set in a wheelchair for seven hours and then are told, "we don't have you today" and they are sent home and die on his way. That may not be the entire story but it is what is repeated over and over.

And I just don't know quite what to do and feel a little bit frustrated and am open to your advice.

Mr. SATO. Mr. McEwen, in the Cincinnati case itself, I think all of us—

Mr. MCEWEN. Remember Harvey is different from what I'm referring to. I'm talking about—

Mr. SATO. Yes.

Mr. MCEWEN. Harvey is just the capstone on a growing frustration.

Mr. SATO. He just happened to be one of the cases within the allegation against Chief Wilson.

As you know, Mr. McEwen, earlier there was an FBI investigation in process. And while that investigation was ongoing, any further work, of course, from my office was suspended. That's in accordance with law. When that report was completed the Office of Special Counsel pursued the allegation regarding reprisal. And while that investigation was going on, my hands are tied and we are currently awaiting the report from the Office of Special Counsel. That, unfortunately, has been one of the reasons for the extended delay, but it's really been within the jurisdiction of other organizations outside the Veterans' Administration.

Mr. MCEWEN. My bill would establish an Assistant Chief Medical Director that would make it possible for you to proceed and not wait for OPM and everybody else in the world to file their reports. Wouldn't that be advantageous?

[No response.]

Mr. MCEWEN. Thank you. You've answered my question.

Dr. GRONVALL. Mr. McEwen, if I may add a comment to the basic question that you asked Mr. Sato, my judgement is that the central office staff of the Department of Medicine and Surgery is not adequate to the task that we face in maintaining administrative support and administrative control of the department.

In the past 2 years as a result of the appropriation our central office staff has been cut over 25 percent at a time when our medical care program has expanded. The staffing in our hospitals has expanded, and the requirements for accountability of programs have also expanded. I believe that that reflects a widely held view that no one wants to support central administrative structures. It's much more appealing to put the funds into direct medical care in our case, and I understand that. As we went through radical reductions of our staff, we attempted to protect certain high priority areas. And we gave disproportionate protection from cuts to the Medical Inspector's Office and the Office of Quality Assurance, and a few other high priority areas in our central administrative staff.

But my answer to you is an easy one. I don't believe the size of our central office administrative staff is now adequate to all of the jobs that we face. I would hasten to add that if it were expanded again, I would not ever promise in advance that some of the individual tragedies that do occur would no longer occur. I think that's beyond the realm of prevention, no matter how strong or expansive a central office administrative structure or quality assurance review mechanism might be.

Mr. MCEWEN. But if it were a separate position, then would it not be protected slightly from these additional barrages on an annual basis? And could it not function with a little bit more autonomy that would be beneficial to the system as it continues to expand?

Dr. GRONVALL. Well my responsibility is to administer a total medical program. So that includes all of the dimensions of developing, operating hospitals and recruiting staff. If a particular piece of legislation defines and mandates a certain defined structure and staffing to one part of my office, yes, your presumption is correct that that protects that one function.

My view, since I'm responsible for the whole administrative structure, is that that reduces my ability to do my total job since it freezes in place by statutory mandate one particular function but doesn't take into account all of the other administrative and program development and management needs of the total administrative responsibility that I have.

Mr. MCEWEN. A final point—

Dr. GRONVALL. Typically also when that's done in legislation no new resources are made available, so the mandate of that kind of legislation results in redistribution from other areas which already maybe understaffed since we now have a law that mandates a certain level of staffing in one office. And I view that as a negative occurrence in terms of the total job to be done.

Mr. MCEWEN. Thank you.

Mr. PENNY. Mr. Smith, do you have a problem or a question?

Mr. SMITH of New Jersey. Mr. Chairman, unfortunately I will not be able to return for this hearing. I have a Foreign Affairs Subcommittee on Human Rights hearing on El Salvador, and I really have to be there. But I do have four questions for Dr. Timothy Condon, and additional questions for the PVA. I would ask that they be made part of the record and the answers provided by our witnesses.

Mr. PENNY. They will be submitted to the witnesses and the questions and answers will become part of the committee record.

[The information appears on p. 75.]

Mr. PENNY. I want to keep things moving here, and Mr. Harris is going to come back and rotate in the Chair so that I can get over for that vote.

We'll dismiss this panel with our thanks for your testimony this morning.

I'm changing the order of the next two witnesses. I'll call Mr. Gordon Mansfield of the Paralyzed Veterans of America as the next witness, as he has a serious family problem in Florida and needs to catch an early flight. I'm certain that everyone will understand and agree. We will then revert to Mr. Timothy Condon and then conclude with our witnesses from the various veterans' organizations.

Mr. Mansfield, come forward and make your presentation. And if you would, identify the staff person that accompanies you and you're free to summarize as you wish. Your entire text will appear in the committee record.

STATEMENT OF GORDON H. MANSFIELD, ASSOCIATE EXECUTIVE DIRECTOR FOR GOVERNMENT RELATIONS, PARALYZED VETERANS OF AMERICA

Mr. MANSFIELD. Thank you, Mr. Chairman.

I am Gordon H. Mansfield, Associate Executive Director for Government Relations of the Paralyzed Veterans of America. And I am accompanied today by Ms. Tina Alvarado, who is a legislative research specialist and also a registered nurse and very knowledgeable in this area.

What I'd like to do, as you mentioned, is summarize my written testimony and I ask that thecomplete written testimony be included in the record.

Mr. Chairman, and members of the subcommittee, it is a pleasure for Paralyzed Veterans of America to appear today and present the views and concerns of its membership regarding procreative services to service-connected veterans.

On behalf of the membership of Paralyzed Veterans of America, we want to extend our appreciation to the Subcommittee Chairman and his staff for their efforts to conduct this vital hearing. As you are undoubtedly aware, PVA has been in the forefront for a number of years conducting research and attempting to increase awareness of procreative disabilities. A disability which is particularly painful since it is one that may involve the veteran's inability to have children. It is also a disability which, for too long now, has gone virtually unnoticed except, of course, by those individuals who as a direct result of service to their country, will never be able to parent children unless certain essential medical services can be provided.

Up until a few years ago most spinal cord injured males were told two things. First, you will never walk again. And second, you will never have children. Today, thanks to advancing technology for many spinal cord injured veterans the latter case does not have to be true any more.

I wish to emphasize that the specific legislation, H.R. 3161, is a very carefully crafted and purposefully limited measure. The legislation authorizes services within reasonable limits of acceptable medical standards to achieve pregnancy in a veteran in conjunction with a veteran's spouse, or in a veteran spouse in conjunction with a veteran by correcting or enhancing the procreative ability of the veteran where such services are necessary to overcome a service-connected disability impairing the veteran's procreative abilities. The language of the bill limits the authorization to include only those services which correct or enhance the existing procreative ability of the service-connected disabled veteran.

The question of surrogate services, services to significant others, the use of a donor egg or sperm, are likewise ruled out by the language, which specifies that the services be provided only to the veteran or if necessary, the veteran's spouse.

As an example, in 1985 PVA became involved in the case of a woman veteran, who as a result of a service-connected gynecological order, was unable to achieve pregnancy. Although she was at the time receiving monthly compensation for her disability, she was denied by the VA her request for in vitro fertilization procedures. When an appeal was made to the agency, the opinion of the General Counsel was the VA has no legal authority to provide services such as in vitro fertilization, or artificial insemination to help overcome a service-connected disability which makes the veteran unable to procreate.

The VA argued that certain infertility treatments will not repair or cure or result in decided improvement of the disability, so therefore medical care cannot be provided under current VA policy. PVA believes that if this statement was consistent across all current VA policies, items such as prosthetics, orthotics and sensory

AIDS could not be authorized, since they neither repair nor cure, but are rather a service to overcome the resulting effect of the disability. And you have in front of you, underneath me, an example of what we're talking about, the wheelchair and what it does.

From there, it follows logically that certain fertility services also help overcome specific service-connected disabilities. It seems unconscionable that the VA will provide a veteran compensation for the loss or loss of use of one or more creative organs under Section 314(K) of Title 38, but will not afford the same veteran access to medical care to mitigate the resultant condition. It is also inequitable that the Department of Defense hospitals will provide certain fertility services to active duty servicemen, or women or retirees, but such services are not available to veterans whose disability is a direct result of their military service.

It is also important to note that in the experience of PVA, in our specific veteran population, in vitro fertilization is the exception rather than the rule. Much more common are other services which achieve the desired result.

I see the red light is on, Mr. Chairman. And what I would like to do is summarize my summary. A person serves in the Armed Forces of the United States of America. He or she incurs a disability which does not allow them to procreate or to parent children. The VA is the medical care provider designated to provide care to service-connected disabled veterans. Medical services in the United States of America, whose technology has advanced, such medical service can overcome this disability. PVA feels it is time to authorize the VA to provide current medical services to service-connected disabled veterans to overcome procreative disabilities.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Mansfield appears on p. 48.]

Mr. HARRIS [Presiding]. Thank you, Mr. Mansfield.

I have a couple of questions. The VA raised the issue of regulating the number of attempts per veteran of a procreative service. And I'd like to have your response to that issue.

Mr. MANSFIELD. Mr. Chairman, my first thought when that issue was raised was that I hope you realize that the difference between one, and two, and three and none is absolute. I'm concerned right now about getting the VA authorized to do one. If they want to write some regulations concerning where you go from there, we'd be happy to work with them. But I hope you understand our concern. It's an absolute difference. One, two or three is completely different than none. And that's our situation right now.

Mr. HARRIS. All right, sir.

And what do you think is the perception among your members about the quality of VA care?

Mr. MANSFIELD. PVA's members, perhaps more so than any other veterans' service organization are dependent upon health care as the basis for life. When you're a paraplegic or when your a quadriplegic, health care is the basic issue because if you do not have that then you're not going to be around here and you don't need the other services. So we're very concerned about this.

We attempt to work with the Department of Medicine and Surgery. PVA would like to see everything possible done to assure that the VA does provide quality care to its veterans.

Mr. HARRIS. Well, do you think that the establishment of a new structure and organization of the medical inspector would effect the perception?

Mr. MANSFIELD. Perhaps that's the key question, Mr. Chairman, a question raised earlier, the perception versus the reality. As some folks are aware, we had some discussions with the Chairman concerning a letter to the editor that PVA had publicized after this report was released. I think the key to the answer is that we feel that the report showed that there are problems or they may be problems, which is the perception. And the perception needs to be taken care of.

Mr. HARRIS. I would turn it over for questions to other members, but we're right in the middle of a vote. And I'm sure they'll be back in a few minutes, and if any of them have any questions of you specifically, I'm sure that we can call you back for that.

Oh, he's got to make an airplane. He doesn't want to be called back then, does he?

We'll submit them for the record, so that you'd have a chance to respond.

Mr. MANSFIELD. Thank you very much.

Mr. HARRIS. Thank you so much.

Next we would call up Mr. Timothy Condon, who is an analyst for the Office of Technology Assessment.

If you would proceed?

STATEMENT OF TIMOTHY CONDON, ANALYST, OFFICE OF TECHNOLOGY ASSESSMENT

Mr. CONDON. Thank you, Mr. Chairman. I ask that my previously submitted written statement be included in the record, and I'll try to summarize it briefly here.

Mr. HARRIS. It will be included without objection.

Mr. CONDON. I'm Tim Condon from the Biological Applications Program at the Office of Technology Assessment. I presently serve as an analyst for the ongoing OTA assessment of the Prevention and Treatment of Infertility.

This morning I will briefly describe some of the medical practices that are currently known as infertility services, including some that may have particular relevance to the reproductive health of veterans.

There are many factors that cause or contribute to infertility. Historically, infertility was thought to be a dysfunction of the female reproductive system. However, today, both male and female factors are believed to contribute equally to infertility. Since male infertility problems have not been studied as extensively as those of females, much less is currently known about the causes and the treatment of infertility in males.

Causes of female infertility can be classified to at least three broad categories: One, defects in egg production; two, defects in the fallopian tubes, that is blockage or damage of the female reproductive tract which will inhibit the transport of sperm or eggs; and three, implantation problems, failure of the fertilized eggs to implant in the uterus.

Male infertility, on the other hand, may be broken down into two broad categories: One, defects in spermatogenesis, that is the production of viable sperm; and two, defects in the transmission of sperm from the testes to the female reproductive tract such as in cases of impotence.

In recent years many new sophisticated technologies, such as in vitro fertilization, have been developed to treat infertility. In addition to these new reproductive technologies great progress has been made with more traditional medical and surgical procedures, such as drug therapy, artificial insemination, and reproductive tract surgery. These more traditional approaches, at present, account for the overwhelming majority of infertility services.

One major cause of female infertility involves ovulation failure. In some cases this complex process which involves the brain, the pituitary, and the ovaries breaks down. The result can be failure of the egg to develop properly or to be released. To correct this condition a number of therapeutic agents may be used. The most commonly employed are known as fertility drugs. These drugs work to mimic, enhance, or augment the natural hormonal state thus stimulating egg production, oftentimes multiple eggs. In some patients egg production and fertilization may be normal but the lining of the uterus fails to develop properly to allow implantation of the embryo. Administration of the hormone progesterone, which normally prepares the uterus for implantation can often facilitate this process.

Although these therapies are highly effective treatments for female infertility, the efficacy of drug and hormonal therapies in the majority of male infertility patients remains unclear and are not commonly practiced.

Surgical treatment of the reproductive tract remains a popular approach to some infertility problems both for the male and female. Although there are many different surgical procedures, I'll just mention one or two here.

Obstructions in the reproductive tract, caused by either infections, previous surgery, or failure to properly develop, are frequent cause of infertility. In the female these obstructions can block the movement of eggs from the ovaries to the other parts of the reproductive tract where fertilization would normally take place. Obstruction in the male, of course, can prevent the release of sperm during ejaculation. Surgical correction for these problems can be frequently accomplished by the skilled surgeon. With the aid of a microscope, fine surgical instruments and much practice, the microsurgeon can locate and remove the damaged portion of the tube. The two ends of the tubes are then cleared of any material and joined together. With the increased requests for reversal of tubal ligation and the reversal of vasectomies, these microsurgical techniques have improved in recent years.

In some cases of infertility the immune system of the female or the male partner will produce antibodies against sperm. And these antibodies, if present in the male, will decrease the quality and the viability of the sperm. If present in the female reproductive tract, these antibodies can inhibit sperm transport and the interaction of the sperm and the egg. Hormone therapy is successful in some cases, like to decrease these antibodies production by the immune

system. If reduction is not accomplished by this means, treatment such as in vitro fertilization, artificial insemination or gamete intrafallopian transfer may be appropriate treatments to circumvent this condition.

In vitro fertilization and embryo transfer is a highly sophisticated infertility treatment that has received much attention in recent years. This treatment involves obtaining mature eggs through surgical procedure, such as laparoscopy, or nonsurgical means, such as ultrasound guided egg-retrieval. These mature eggs are produced by natural ovulatory cycles, or more frequently, induced by fertility drugs. Once the eggs are collected, their maturity is assessed under a microscope and fertilization of the mature eggs is attempted with sperm collected from the husband, or the donor. Sperm and eggs are mixed in a culture dish to achieve this fertilization and are allowed to sit for approximately 18 hours. Eggs are then examined to see if fertilization has occurred. If fertilization has occurred, usually within 36 to 48 hours the eggs will begin to divide and the embryos may be transferred to the uterine cavity. If the embryo implants in the uterus, small increases in human chorionic gonadotropin, the pregnancy hormone, can be measured in the blood and urine.

I'll just summarize here, artificial insemination. Artificial insemination is one of the oldest forms of infertility treatment. the practice of artificial insemination is usually classified as using the husband's sperm or donor sperm. In each one of these situations sperm can be placed within the female reproductive tract. All inseminations are performed around the time of either drug-induced or natural ovulation.

Practices vary among infertility programs, however. Multiple inseminations during each fertile period are usually performed to increase the likelihood of conception.

In summary, there are a variety of traditional and more recently developed medical and surgical treatments for infertility treatment. Treatments often involve both members of a couple, each of whom may have a condition that causes subfertility. Medical treatment can range from instruction of the couple in the relatively simple techniques of pinpointing ovulation and the timing of intercourse, to more complex treatments involving ovulation induction and fertility drugs, artificial insemination or in vitro fertilization. Surgical treatments also span a wide spectrum.

Although new reproductive technologies offer great promise for many infertility patients who would not otherwise be able to be treated, new discoveries and improvements of more traditional treatments make these approaches the most popular at this time. It is also important to note that even complex and sophisticated treatment of one partner will be of no benefit if the other partner suffers from undiagnosed infertility. Therefore, unlike most other areas of medical treatment, the couple as a unit is properly considered to be the infertility patient.

Thank you, Mr. Chairman. I'll be pleased to answer any questions at this time.

[The prepared statement of Mr. Condon appears on p. 54.]

Mr. PENNY [Presiding]. Thank you, Mr. Condon.

In light of your last remarks, I may have a sense of your answer to this question, but let me raise the issue. Is it possible, in your opinion to think of fertility or procreative services as divisible into male components and female components? The VA raised the point that procreation services involve a treatment or intervention primarily directed to a non-veteran spouse, and in light of that statement I'd appreciate your answer.

Mr. CONDON. We would say that I believe most experts in the field of infertility treatment would say that the couple as a unit must be considered the infertility patient. On a case-by-case basis, if one was to examine the male or the female and find a defect without knowing what was in fact the fertility of the partner, treatment therefore would not be successful.

Mr. PENNY. So we could divide the services once the problem was identified, but in terms of identifying the total infertility situation, both spouses would have to be involved?

Mr. CONDON. Both spouses would need to be evaluated if—

Mr. PENNY. And your recommendation would be that at least to that stage in terms of identifying the problem that the VA should offer those diagnostic services to both individuals?

Mr. CONDON. Well, Mr. Chairman, as you know, the Office of Technology Assessment wouldn't make a recommendation in this case.

Mr. PENNY. Let me move on to the outlook for fertility in paraplegic men after spinal cord injury. Apparently the prognosis isn't very good in most of those cases. What is the quantitative impact on veterans who might use procreative services, and the type of services they might use? The PVA, for instance, says that among their membership retrieval of sperm and subsequent artificial insemination of the veteran spouse is fairly common.

Mr. CONDON. As part of our assessment we right now do not have any figures as to the level of practice of artificial insemination for paralyzed individuals. There are two problems that usually come up in the cases of spinal cord injury patients, which are in the written statement. And those, of course, are transmission of the sperm to the female reproductive tract, but also often times there is a decreased quality in number of sperm. And in some cases special techniques, special considerations such as either artificial insemination or in vitro would be appropriate in terms of success.

Mr. PENNY. In the VA's testimony the issue was raised about how many unsuccessful procedures should be attempted for one veteran. Can you speak to this issue generally or specifically related to types of treatments?

Mr. CONDON. As I mentioned for artificial insemination, common practice, I believe, is there would be multiple inseminations during every fertile period during any given month. But also, because of the reasonably simple technique, that may go on for a number of months if it wasn't successful.

In the case of something like in vitro fertilization it's not clear what the current level of practice is. Depending on the success of the in vitro fertilization program, the level of insurance reimbursement that the couple, and now we're talking general practice here, the level of insurance reimbursement, or the financial security of

the couple themselves will determine how many attempts of IVF they might use.

Mr. PENNY. I have one last question.

PVA quotes a VA cost estimate of $580,000 in the first year of enactment of H.R. 3161. What cost estimates can you make with regard to the VA and procreative services?

Mr. CONDON. Mr. Chairman, we're currently working on that with the VA and some economists who are familiar with the VA system. We hope to report those numbers to the Congress either later this year or the beginning of next year when our report is released.

Mr. PENNY. We appreciate that and look forward to your office submitting that report to this committee.

Mr. CONDON. Thank you, Mr. Chairman.

Mr. PENNY. I don't have any further questions. Does the staff have any questions they want to pursue?

Mr. KINGSTON SMITH. [Minority Deputy Chief Counsel] Yes, Mr. Chairman. I have one question.

Is in vitro fertilization now considered a standard medical treatment, or is it still considered experimental?

Mr. CONDON. Well, it's a very interesting question that we've been discussing at the Office of Technology Assessment for about a year now as part of our assessment. We have come to no conclusion on that point. But I'll tell you that some of the things that we've considered is that some medical insurance or health insurance companies, consider it experimental and therefore exclude it from coverage.

Certainly some of the most prominent or prestigious in vitro fertilization programs in the country, such as the Jones Institute, who are very successful with this technique, would not consider it experimental. Again, couples who have one or perhaps in some cases two babies born by this technique might not consider it experimental. But it's still a question that's up in the air.

Mr. KINGSTON SMITH. Thank you.

Mr. PENNY. Thank you, Mr. Condon for your testimony.

The last group, I would like to bring forward as a panel. It includes Mr. Philip Riggin, Director of National Legislative Commission of the American Legion. He will be accompanied by Mr. Robert Lyngh, Director, National Veterans' Affairs and Rehabilitation Commission. I'd also like to call for this panel, Mr. David Gorman, Assistant National Legislative Director, Disabled American Veterans, and Mr. Dennis Cullinan, Assistant Director, National Legislative Services, Veterans of Foreign Wars.

I would ask that you make your presentations in the order that I have called you forward, and as always you are free to summarize your remarks. Your entire written presentation will appear in the committee record.

Mr. Riggin?

STATEMENT OF E. PHILIP RIGGIN, DIRECTOR, NATIONAL LEGISLATIVE COMMISSION, THE AMERICAN LEGION

Mr. RIGGIN. Thank you, Mr. Chairman. We will certainly summarize very quickly.

The American Legion, again, is pleased to have the opportunity to appear before this subcommittee, and in making this appearance one day after the presentation of our National Commander on Legislative Priorities for the upcoming year, we appreciate the full committee's reception of our National Commander yesterday. We do deeply appreciate that.

We're going to limit our comments, Mr. Chairman, this morning to those provisions within S. 1464 that deal with various proposals affecting quality assurance of medical care within VA.

Title II of S. 1464 deals with quality assurance and independent inspections within the VA as they relate to veterans health care. It seems that these provisions are being considered as a direct result of reports issued earlier this year by the House Committee on Government Operations and by the General Accounting Office, both of which question the reliability of quality assurance within VA.

With that in mind, we would first like to say that the reports mentioned earlier do have some merit and some substance. We're also aware that VA is responding to both of these reports, agreeing in some measures and disagreeing in others. We believe that the VA response has been a valid one. The point being that VA is so vast and so complex that it is inevitable that problems will arise. Some may be systemic while others may pertain to isolated incidents.

We believe that VA is making a good faith effort to improve both care-delivery and quality assurance. And we believe that the methodology for reporting accidents and incidents needs to be improved at the station level to ensure that serious incidents do not escape the notice of central office so that appropriate action can be taken when indicated.

The agreed objective is to have a thorough and reliable reporting system, and a method in place that would guarantee appropriate action in the face of any instance of malfeasance or malpractice. With these goals in mind, the American Legion does support the establishment of a medical inspector general and a new position of Assistant Chief Medical Director for quality assurance, with, of course, Congressionally mandated staff support to guarantee effective functioning of both.

We do have two reservations, however, related to the mechanism about the medical IG's requirement to report to the Chief Medical Director. While we know the medical community may not agree with us, we would ask the subcommittee to seriously consider the advisability of attaching the medical IG directly to the office of the Administrator, as is now the case with the VA Inspector General. This proposal would have the medical IG reporting only to the Administrator with complete authority to select matters for medical investigation.

The reason for this suggestion is that the appearance of complete independence from DM&S control is essential to establish the medical IG's credibility with veteran patients, with service organizations as consumers' representatives, and with outside observers who regularly monitor and occasionally report on VA medical practices. We believe that requiring the new position to report to the Chief Medical Director could leave open the continuing possibility of having to defend the medical IG's independence and objectivity

in accomplishing its work. Under these circumstances we fear that the full potential of the medical IG could not, or perhaps would not be achieved.

Secondly, we ask the subcommittee to carefully examine the advisability or the necessity to establish a new position of Assistant Inspector General for Health Care Quality Review in addition to creating the medical IG's position. In our opinion, establishing both would likely produce a redundant layer of inspection activities. This would be particularly the case if, as we suggest, a medical IG is assigned to the Office of the Administrator.

With these adjustments, Mr. Chairman, the American Legion wholeheartedly favors any action that would enhance the VA's ability to assure quality review in its health care delivery program.

That completes our very brief observations on this pending legislation, and I will certainly answer or attempt to answer any questions you may have.

Thank you.

[The prepared statement of Mr. Riggin appears on p. 61.]

Mr. PENNY. Thank you, Mr. Riggin.

Mr. Gorman?

STATEMENT OF DAVID GORMAN, ASSISTANT NATIONAL LEGISLATIVE DIRECTOR, DISABLED AMERICAN VETERANS

Mr. GORMAN. Thank you, Mr. Chairman. Certainly it's a pleasure to appear here this morning.

With respect to H.R. 3161, this measure would authorize the Administrator to provide certain medical services to a veteran to the reasonable extent necessary to overcome the effects of a service-connected disability which prevents or impairs the ability of conceiving a child.

Mr. Chairman, while the DAV has no official position to the perceived intent of this measure, we do feel that explanatory report language is required to express the limitations of this bill.

In particular our interpretation is that the services would be provided simply to achieve pregnancy. Therefore, we do not envision the VA to be required to provide obstetric services, prenatal or postnatal care in conjunction with any successfully achieved pregnancy. We would also raise the issue of the agency's potential liability relating to possible complications and/or permanent disability to the mother or possible birth defects or later disability affecting the child.

Until those questions are fully addressed, Mr. Chairman, the DAV is compelled at this time to withhold its full support of that measure.

With respect to the issue of quality assurance, I would like to relate our views on what we consider to be the two major provisions of the Senate bill, S. 1464.

During September of 1980, the Office of Medical Inspector, as we recognize it today, was administratively established within the Department of Medicine and Surgery.

The medical inspector, who currently reports to the Deputy Chief Medical Director, simply provides support staff to the Chief Medical Director to assure optimal quality care. The medical inspector

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is responsible for monitoring, investigating and reviewing required reports of incidents involving veterans treated in VA medical facilities.

Issued identified by the medical inspector as requiring corrective action are, to our knowledge, to be implemented by the regional directors.

As you are aware, Mr. Chairman, and it's been discussed this morning, the General Accounting Office has released two reports, one during June of 1985 and again during May of 1987, both relating to the VA's quality assurance programs. Both of these reports identified rather major failures on the part of the VA, the Department of Medicine and Surgery and the Medical Inspector to provide adequate oversight and supervision of portions of the VA's quality assurance endeavors.

The results of the GAO efforts has opened the door to an argument regarding the degree of quality assurance within the agency. Some would argue that the VA's quality assurance efforts are being portrayed as grossly ineffective while others argue that the issue of quality assurance standards and efforts were not actually being called into question by GAO.

While we are uncertain as to the correctness of either position, we are extremely concerned and aware of the fact that the intent of the function of the medical inspector is certainly being placed in a tenuous position at this time.

Mr. Chairman, the other portion of the quality assurance question relates to the statutory creation within the Inspector General's Office of an assistant inspector general for quality assurance health care review. In our view the intent of such a proposal is meritorious and should be seriously considered by the subcommittee.

As we understand it, the Office of Inspector General is responsible for performing oversight reviews of all quality of care medical investigations undertaken by the Medical Inspector within the Department of Medicine and Surgery.

Lacking adequate in-house medical expertise, the IG attempts to use more or less of a common sense approach when making evaluations and determinations of the sufficiency of the Medical Inspector's activities. An obvious problem with this approach is that the IG cannot fully evaluate issues of a purely medical nature and be able to state with any degree of credibility that the medical inspector's findings and actions are or are not appropriate. Utilizing this approach it appears reasonable that the IG sometimes may be faced with challenging the medical opinions and positions taken by the medical inspector.

Additionally, Mr. Chairman, we have long been concerned, and we have related our views to the VA, with the scope and certain specific findings identified in numerous IG audits of various VA medical facilities.

For example, it is not uncommon for the IG to conclude and recommend during their cyclical audit processes that veterans' inpatient length of stays could be reduced; that veterans' transfer/discharge from a period of hospitalization was not timely; that veterans should be placed in more appropriate care environments; and

these type of medical opinions are constantly related in the audits throughout.

Issues such as these obviously have a direct relationship and impact on how medicine is being practiced in the VA health care system and how medical services are being furnished to disabled veterans.

In our view, these types of questions and situations are of vital importance to the mission of DM&S to provide quality health care services. There must exist a viable and objective mechanism to resolve these questions to the satisfaction of all interested parties. And this is currently not the case.

In the eyes of many there is a lack of credible, objective overview concerning the VA's health care programs. Whatever oversight and investigations that are done of DM&S is done by DM&S.

Perceptually, this is an unhealthy situation and perception, accurate or not, by the many observers and the stockholders of the VA system is critical.

Mr. Chairman, we have attempted to relate our views regarding the important, though complex, issue of quality assurance. Conceptually, we feel the provisions of S. 1464 to be valid and certainly required at this time.

It is our belief that the VA health care system does, in fact, provide quality health care to those eligible veterans who utilize the system. However, absent an objective and highly effective quality assurance program, the VA does remain vulnerable to critics of the system.

Time has shown that the VA, as a health care system, is certainly cost-effective in the provision of medical care. Certainly, it is a viable National resource. If any one issue is capable of diminishing or dismantling the system, it is the quality of health care provided. Without quality care, measured and documented by a program of quality assurance, any health care system's demise is probably an eventuality.

Thank you very much, Mr. Chairman. That concludes my statement.

[The prepared statement of Mr. Gorman appears on p. 64.]

Mr. PENNY. Thank you, Mr. Gorman.

Mr. Cullinan?

STATEMENT OF DENNIS CULLINAN, ASSISTANT DIRECTOR, NATIONAL LEGISLATIVE SERVICE, VETERANS OF FOREIGN WARS

Mr. CULLINAN. Thank you, Mr. Chairman, for this opportunity to present the views of the Veterans of Foreign Wars with respect to the several pieces of legislation affecting veterans' health care. The VFW wishes to thank the Chairman and the members of the subcommittee for holding this hearing and including our organization in the on-going process of refining and improving health care services afforded to this Nation's veterans.

The first bill under consideration today is H.R. 3161, which would amend Title 38 to authorize certain additional medical services for veterans with service-connected disabilities. More specifically, the Administrator of the VA would be authorized to provide medical services to a veteran, and if necessary the veteran's

spouse, to overcome the effects of a service-connected disability which prevents or impairs the ability of the veteran and the veteran's spouse to conceive a child. This bill enjoys the strong support of the Veterans of Foreign Wars. The VFW feels that such a program is long overdue. We welcome its implementation by the VA both through its own facilities and, as necessary, on a contractual basis with the private sector. There can be no doubt that such an impairment has a strongly detrimental social and psychological consequences for such any so afflicted veteran.

The last proposal under consideration today is Title II of S. 1464, as amended, concerning the need to improve the oversight of the VA Quality Assurance Program. This proposal would establish in the office of the Chief Medical Director, an Office of Medical Inspector General. This office would be headed by the Medical Inspector General who would be directly responsible to the CMD.

This bill also would create an Assistant Chief Medical Director for quality assurance who would also be a qualified physician and who would be responsible to the CMD for carrying out the responsibilities assigned by him. The position would be responsible for monitoring through reviews of VA health care facilities the establishment and implementation of health care quality assurance and risk management programs of the Department of Medicine and Surgery.

Furthermore, the position would also be tasked with monitoring the activities of the Medical Inspector General to include recommending that he conduct investigations.

VFW is highly concerned with the need to improve oversight of the VA Quality Assurance Program. Furthermore, we very much concur with the assertion that if veterans, the Congress and the American people are to maintain confidence in the VA health care system, we must be assured that the VA is delivering high quality health care. However, we would point out that the VA currently has in place the Office of Quality Assurance and the Office of Medical Inspector, both serving in a watchdog capacity with the DM&S. While the VFW has had occasion in the past to be critical of the Office of Medical Inspector, we believe the problems that exist can be rectified. Of major concern is the current lack of adequate staffing and funding.

We are of the opinion that the provision of additional funding to provide increased staff will enhance the capability of the office to properly implement its mandated role. We also believe that the Medical Inspector General should have greater latitude to contract for top quality medical experts who would be able to assist the office in specific situations through the utilization of their unbiased judgement and medical expertise. While the Medical Inspector does now have this authority, it should be both expanded and utilized.

We are also of the opinion that the Office of Quality Assurance must be improved. However, in light of the fact that this office is relatively new, we believe that a greater investment of time and attention should first be made to enable it to prove its worth.

For these reasons, the VFW believes for the time being, the VA should turn its attentions and resources to improving its present capabilities rather than creating another mechanism. Should improvement in this most critical area not materialize in the very

near future, however, we would support more drastic remedial action, such as that which is not under consideration here today.

Mr. Chairman, that concludes my statement.

[The prepared statement of Mr. Cullinan appears on p. 70.]

Mr. PENNY. Thank you, Mr. Cullinan.

I had one question designed to get a more specific response about the views of your membership on that quality assurance issue, but in each case your testimony was pretty clear about where your organization comes down and what perception your membership has on this quality matter. And so I don't have to pursue that question.

Mr. Harris, do you have any questions?

Mr. HARRIS. I had the same questions in mind as to the organizations' feelings and perceptions. Of course, perceptions are so important and that's one thing that has concerned me in the eyes of not only myself, but of the veterans, is to how you investigate yourself and do that in such a way that it's perceived by the little old guy that's got the complaint that he got the best possible investigation and handling of the matter.

And I just appreciate all three of your testimony. I'm sorry I was not able to hear all of it, but they've stretched us out pretty thin this morning, as you can see. And I just want to thank you for coming and presenting your views to us.

Thank you, Mr. Chairman.

Mr. PENNY. Thank you.

Again we appreciate your presentation this morning as we do those who preceded you.

And with that, the committee hearing is adjourned.

[Whereupon, at 10:55 a.m., the subcommittee was adjourned.]

APPENDIX

OPENING REMARKS OF
HONORABLE CHRIS SMITH, SUBCOMMITTEE ON
HEALTH AND HOSPITALS,
SEPTEMBER 23, 1987

Thank you Mr. Chairman.

Mr. Chairman, I would like to commend you for your initiative in calling for this hearing today to discuss HR 3161, a bill to provide procreative benefits to service-connected disabled veterans, and S. 1464, which in part, provides for the establishment of a VA Medical Inspector General.

Mr. Chairman, I would like to take this opportunity to express my grave concerns regarding the provision of some services which may result from passage of HR 3161. The language in HR 3161 does not exclude in vitro fertilization as an option for a couple attempting to conceive a child. Based on some of the advance testimony from the PVA and Dr. Timothy Condon of the Office of Technology Assessment, funding for in vitro fertilization is assumed and taken as a given. That, I believe, raises considerable moral and ethical problems. As our committee continues its consideration of this bill, I think it is important to recognize some facts concerning in vitro fertilization.

According to Dr. Mishell, Professor and Chairman, Department of Obstetrics and Gynocology, University of Southern California, Los Angeles, "the chances of taking a baby home per in-vitro fertilization cycle (IVF) are 5-7% and the woman must be prepared to undergo at least six treatment cycles to improve chances for success." With an average cost of 4,500 - 6,000 dollars per treatment cycle, "successful" IVF may cost as much as 30,000. Only 45 of the 150 IVF clinics in the United States have as yet recorded a single birth.

Mr. Chairman, the potential for excessive costs pale in relation to the destruction of thousands of embryos who are conceived in the petri dish. If we intend to fund in vitro fertilization under the auspices of the VA, we then share at least some of the responsibility for the embryos who are discarded.

Mr. Chairman, our nation does not even have a policy on guidelines to provide for some uniformity among IVF clinics. IVF clinics are not required to keep records concerning treatment success rates. Lastly, no federal agency funds IVF research-- even the Department of Health and Human Resources refuses to supply funds of any kind for these procedures.

Mr. Chairman, in light of these facts, I suggest our subcommittee take a long hard look at the proposal before us and and exclude IVF services from HR 3161.

STATEMEMT OF

JOHN A. GRONVALL

CHIEF MEDICAL DIRECTOR

BEFORE THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 1987

Mr. Chairman, we welcome the opportunity to appear before the subcommittee to testify on two diverse legislative proposals.

H.R. 3161 - MEDICAL SERVICES RELATING TO CONCEPTION

H.R. 3161, a bill introduced by request, would authorize the VA to provide medical services to a veteran, or a veteran's spouse, to assist the couple in attempting to conceive a child if they are unable to do so naturally due to a service-connected disability. The bill would amend 38 U.S.C. § 612, authorizing services on an outpatient basis only. Further, it would specifically exclude services involving use of surrogate mothers, or the sperm or egg cells of anyone other than the veteran or the veteran's spouse.

As you are aware, the issue of whether the VA can and should

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furnish certain disabled veterans, or their spouses with such services as artificial insemination, or in vitro fertilization, has been before the VA for some time. It has arisen primarily in two types of cases; (a) those cases involving women veterans unable to conceive due to such disorders as, for example, damaged fallopian tubes resulting from service-connected pelvic inflammatory disease, and (b) cases involving male veterans with spinal cord injuries. With respect to the first case, it was determined over two years ago that VA could legally furnish service-connected women veterans with so called "reproductive" services only if it could be said that their inability to become pregnant is a disability distinct from the specific physical disability which prevents conception. Whether the inability to procreate is a disability in and of itself is subject to debate. In the second case, VA is legally unable to furnish "reproductive" services to the nonveteran wives of male veterans with spinal cord injuries because VA has legal authority to furnish hospital care and medical services only to veterans, and services such as in vitro fertilization and artificial insemination involve treatment of the nonveteran wife, not the disabled veteran husband.

The proposed enactment of H.R. 3161 raises many difficult questions. While it is a measure which may appear to involve only a relatively small number of veterans and thus to have only minimal impact, its enactment would represent a

substantial change in the VA health care mission. Not only would it, in most cases, involve providing very specialized services to nonveteran spouses, but these would be elective services which are not targeted to cure or treat a disease or disability. Certainly, spouses are involved in many types of VA treatment, particularly psychiatric counseling and treatment. But procreation services carry this a step further in that the treatment or intervention is primarily directed to the nonveteran partner. Provision of services to overcome infertility would represent an extension of services beyond the long-standing VA role of providing care to treat a disability or disease. Indeed, in its generality, the bill could even be read to authorize obstetrical care if that were deemed "reasonably necessary," by reason of financial need, for example.

To our knowledge, no other Federal program provides benefits of the type contemplated by this bill. While its novelty is not in itself a basis for rejecting this proposal, it raises profoundly difficult philosophical and practical questions. Heartwarming accounts of couples' achieving their deepest hopes through the intervention of medical and reproductive technology should not obscure the troublesome questions associated with asking the Government to become involved, as it necessarily will, in regulating access to the gift of birth. For example, what steps is an administering agency to take in the case of an

otherwise eligible couple who has a high probability of producing a profoundly retarded child, but insist on availing themselves of this benefit? What actions should be taken in the case of a veteran or a spouse (or both) who has a severe psychiatric condition or a history of abusive behavior?

This bill would authorize services "to the extent reasonably necessary" to overcome infertility. The bill does not address, however, either the very practical question of how many unsuccessful procedures may be attempted under its auspices, or broader questions of family size. Is this benefit intended to enable the veteran to overcome infertility and have a child? Two? More? Is age or health status to be a limiting factor? What if only untested, experimental procedures offer any hope of success for a particular couple? We do not have the answers, but pose these as among the kind of questions for which we think there must be answers before such far-reaching legislation is considered for enactment. Accordingly, we cannot support enactment of H.R. 3161 at this time.

HEALTH CARE QUALITY ASSURANCE LEGISLATION

Mr. Chairman, I will next address myself to title II of S. 1464, legislation pending before the Senate which is concerned with medical quality assurance in the VA. We are grateful for the opportunity to provide views on the measure to assist you

in your deliberations if the bill is enacted by the Senate. In essence, we strongly oppose the enactment of title II of S. 1464.

That proposal has four specific parts. It would establish an Office of Medical Inspector General in the Office of the Chief Medical Director. It would require appointment in DM&S of an Assistant Chief Medical Director for Quality Assurance. It would establish the position of Assistant Inspector General for Health Care Quality Assurance Review in the Office of the Inspector General. And finally, it would direct that the CMD ensure that departmental employees be periodically instructed in their quality assurance responsibilities, and be disciplined for failure to comply with required quality assurance procedures.

I will first address myself to the requirement that VA have an autonomous Medical Inspector General (MIG) within the Department of Medicine and Surgery (DM&S). Under this very prescriptive measure, the MIG's office would be staffed with personnel who have medical training as physicians, dentists, and nurses. The MIG would independently conduct inquiries into the quality of patient care, and would have the authority to recommend disciplinary action and to refer cases to prosecutorial agencies. Creation of this position by statute would, in our view, be an excessive response to a longstanding

issue within the medical profession: how best to manage the inquiry into professional matters when treatment outcomes are unfavorable or injurious. The VA already has in place an effective mechanism for addressing this issue in the form of a Medical Inspector. The VA can certainly improve on its already commendable record in this area, and is doing so by augmenting the staffing of the Medical Inspector's office, but the enactment of this proposal would burden rather than enhance our efforts.

The creation, by statute, of an autonomous MIG would tend to create the perception in DM&S that the office is being established to perform a somewhat more punitive, or regulatory role than is now the case. The current Medical Inspector enjoys significant autonomy, and he also enjoys excellent cooperation from physicians and other health care providers in the Department who view the office as one part of the larger DM&S quality assurance effort. The Senate Committee's proposal, by giving the MIG independent statutory authority, would foster the perception that the MIG is a separate entity in the Department, and somewhat of an adversary. In our view, that could breed mistrust and misunderstanding, and result in a tendency to be less cooperative in the efforts of the MIG. This more adversarial role could seriously interfere with the collegial process that is so critical to a productive Quality Assurance (QA) program.

The mainstay of VA's QA program is, and should remain, the peer review process already in place. Peer review is a process that has proven its worth both in the private sector and in government institutions. Peer review focuses on problem-solving rather than polarization and the fixing of blame. Peer review results in determinations aimed at ensuring that unfavorable circumstances will not reoccur, rather than punishing human errors that are usually not blameworthy. Our quality assurance program can truly be described as an ongoing, efficient, flexible, integrated health care monitoring and improvement system. The program not only calls for continuous monitoring of certain routine health care functions and procedures, but also provides for comprehensive review of unusual, unexpected or unfavorable incidents which a patient may experience. In addition, the program includes: reviews to determine if health care utilization is effective; problem focused health care evaluations; and systematic review of qualifications of applicants for appointment and of those requesting clinical privileges. The Department's systematic quality assurance "tracking" process, in calendar year 1986, monitored more than 10,000 separate quality assurance recommendations to make sure each was resolved. In sum, the comprehensive system that can best assure quality care is in place and functioning.

As it currently operates, the QA program is both rigorous and objective. For example, working in tandem with the statutory

VA Inspector General, the administratively established Medical Inspector already this fiscal year has completed more than 240 quality of care inquiries. In independently reviewing these cases, the Inspector General has, in 26 of them, raised queries which have been resolved or remain pending with the Medical Inspector's Office. In the 18 month period ending in April 1987, there were more than 2300 field station investigation files received by the Medical Inspector's Office. These, too, are subject to review by the VA Inspector General; a statistical sample of 78 of these matters were substantively reviewed, and followup with the medical facility involved was initiated where, in the independent view of the Inspector General, it was needed. In sum, current procedures bring ample professional oversight and structural independence to bear on the issue of VA health care quality.

The results of systemwide surveys by the Joint Commission on the Accreditation of Hospitals (JCAH) confirm the effectiveness of the current VA quality assurance activities and structure. The Commission, one of some 40 external organizations and agencies which routinely inspect VA health care activities, has established stringent standards for hospital accreditation that consider institutional factors, health care processes, and treatment outcomes. JCAH accreditation reviews, virtually without exception, show individual VA medical centers do not simply meet, but rather exceed, the standards in each of the three areas.

The Senate Committee's desire to improve our QA program is equally our desire. I am committed to reallocating existing resources or making use of newly provided resources for the current QA program. I believe adequate authority exists to make the system even better than it is without the creation of an autonomous Medical Inspector General, which may be more disruptive than helpful.

Mr. Chairman, I also do not believe it necessary to statutorily direct that VA have an additional Assistant Chief Medical Director who shall be a physician with extensive experience in health care quality assurance and risk management. The Department of Medicine and Surgery currently has an Office of Quality Assurance headed by a physician director. I fail to see the need for dictating, by law, the precise title and qualifications of the individual heading that office. Rather, the Chief Medical Director should be given the flexibility to carry out his or her responsibilities, including the responsibility to assure that quality medical care is furnished to veterans, using the management structure he or she believes works best.

Similarly, Mr. Chairman, I do not believe it is necessary to statutorily direct, as the Senate bill would, that the CMD ensure that departmental employees be periodically instructed in their quality assurance responsibilities, and be disciplined

for failure to comply with required quality assurance procedures. In my view, seeing that employees are aware of their quality assurance responsibilities is part of my responsibility, and the responsibility of those working with me in the Department. I know that it is being done now, and I assure you it will continue to be done.

As with the other provisions in the Senate bill, we oppose the section which would establish the position of Assistant Inspector General for Health Care Quality Assurance Review in the Office of the Inspector General. The bill is extraordinary in that it would require the IG to have a specified staff of physicians, dentists, nurses attorneys and other health care professionals to conduct reviews of quality assurance programs and monitor the activities of the Medical Inspector General. In our view, the staffing formula provided in the bill would not promote access to the diversity of experience and expertise that is optimal for effective QA review, and it would lock the Inspector General into a staffing pattern and deprive him of the flexibility needed to respond to changing priorities. Most importantly, it fails to take into account that, under its existing staffing and structure, the IG already provides effective monitoring of the quality assurance program, through a combination of auditing of the QA program and rigorous reviews of the activities of the Medical Inspector.

Furthermore, the IG already has the authority to hire an adequate number of permanent employees or consultants to perform QA reviews.

Mr. Chairman, we believe the Senate legislation was prompted in large part by a May 1987 GAO report on VA's Patient Injury Control Program which pointed out that improvements need to be made in the reporting of patient care incidents in the VA. That is a criticism which needs to be addressed, and is being addressed. However, the GAO certainly did not find that the VA's quality assurance system is gravely flawed, or that care given VA patients does not meet all applicable standards. In our view the Senate legislation represents an overreaction to a very limited problem involving the reporting of patient incidents. The VA should be permitted to address this problem in the context of its existing QA program which is comprehensive, and which has been demonstrated to be effective. We simply question the need for, and therefore oppose, additional legislation in the face of an already extensive statutory scheme, committed program management (both in the Department, Inspector General's Office, and Office of the Administrator of Veterans Affairs), and vigorous oversight, both within VA and the Congress.

Mr. Chairman, this concludes our testimony. My colleagues and I would be pleased to respond to any questions you may have.

STATEMENT OF
GORDON H. MANSFIELD, ASSOCIATE EXECUTIVE DIRECTOR
FOR GOVERNMENT RELATIONS
PARALYZED VETERANS OF AMERICA
BEFORE THE
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
CONCERNING
H.R.3161, LEGISLATION TO PROVIDE PROCREATIVE BENEFITS
TO CERTAIN VETERANS
AND
S.1464, TITLE 2, AS AMENDED, TO ESTABLISH
A MEDICAL INSPECTOR GENERAL WITHIN THE VETERANS ADMINISTRATON
SEPTEMBER 23, 1987

Mr. Chairman and Members of the Subcommittee, it is a pleasure for Paralyzed Veterans of America to appear today and present the views and concerns of its membership regarding two important issues: the provision of procreative services to service-connected veterans, and the establishment of the Office of VA Medical Inspector General.

On behalf of the membership of Paralyzed Veterans of America, we want to extend our appreciation to the Subcommittee Chairman and his fine staff for their efforts to conduct this vital hearing. As you are undoubtedly aware, PVA has been in the forefront for a number of years, conducting research and attempting to increase awareness of procreative disabilities. A disability which is particularly painful since it is one that may involve the veteran's inability to have children. It is also a disability which, for too long now, has gone virtually unnoticed except, of course, by those individuals who, as a direct result of service to their country, will never be able to parent children, unless certain essential medical services can be provided.

I. PVA Background

PVA has, since its formation over forty years ago, been a strong and determined advocate for expansion of roles for disabled individuals and has worked tirelessly to promote improvements in the quality of life. We have come a long way when one considers that most veterans returning home with spinal cord injuries after World War II faced a life expectancy from 6 months to no more than five years. Today, the life expectancy following most spinal cord injuries is comparable to the rest of the population if they survive the initial 6 months after injury. Thanks to the work of this fine Committee and others, not only are these veterans living longer, they are living at home in an accessible environment; sixty-five per cent are driving specially-adapted vehicles; they are enrolled in vocational rehabilitation and education programs; they are becoming successful lawyers, architects, teachers, and even Members of Congress. But there is one area that the VA has overlooked; there is one disability that the VA is not helping to overcome, and as a result, some of these veterans may never know the fulfillment of becoming parents. To PVA, whose job it is to encourage these veterans "to know no boundaries," this is a serious shortcoming.

True rehabilitation involves not only the individual, but society as a whole. It is a two-way street. PVA has worked to educate the public regarding disabilities with the hope that certain existing attitudinal barriers would be removed. With your help, we have already realized many successes in this arena. Although, in general, society is accepting and promoting the reentry of disabled individuals into mainstream life activities, we still have a long way to go.

In 1977, PVA became closely involved in the case of a male, quadriplegic veteran who, because of his service-connected physical handicap, was denied custody of his two sons by the court (Marriage of Carney, 24 CAL. 3rd 728

(1979)). The case is relevant to today's testimony, because it clearly illustrates the uphill battle against attitudinal barriers and negative stereotypes with which our membership are continually confronted.

The veteran and the veteran's wife separated in 1972, leaving the father in sole custody of their two young sons. From 1972-1977, the mother did not once visit her sons, although she did make infrequent contacts by telephone and mail. In May, 1977, the father filed for dissolution of the marriage, and the mother filed for immediate custody and won. It appeared that the opinion of the presiding judge was that, since the father would not be able to participate with his sons in sports and other physical activities, "it wouldn't be a normal relationship between father and boys." The decision was rendered despite the testimony of a clinical psychologist who stated that his professional opinion was that the children did not appear threatened by their father's physical condition; and that the condition did not in any way hinder his ability to be a father and would not be a detriment to them. All in all, the psychologist believed that the father was the more consistent, stable part of this family, and that their present situation was a healthy environment for the children. He pointed out to the judge that, although this father would not be able to actually play ball with his sons, he was, in fact, able to drive them to the games, coach them, or even umpire, cheer and give encouragement as a fan, drive them home and even buy them an ice cream cone on the way.

This story has a happy ending. The opinion was reversed in the Court of Appeals, which found that the previous opinion was based on negative stereotypes and denied the civil rights of handicapped parents. The point we are making is this: rehabilitation is two-fold, consisting of the individual and the willingness of society to allow for an ever-increasing expansion of roles by disabled individuals. If we are to bar access of this individual, because of his disability, into any role which he is capable of fulfilling in a free and democratic society, are not we too, in essence, barring that individual's civil rights? Is denying the service-connected disabled veteran access to existing medical technologies, which could result in the ability to conceive children, not analogous to barring that same individual the right to vote, because of the long flight of steps leading to the polling place? A more recent example, in 1985, PVA became involved in a case of a woman veteran who, as a result of a service-connected gynecological disorder, was unable to achieve pregnancy. Although she was, at the time, receiving monthly compensation for her disability, she was denied, by the VA, her request for in vitro fertilization procedures. When an appeal was made to the agency, the opinion of the general counsel was that the VA has no legal authority to provide services such as in vitro fertilization, or artificial insemination to help overcome a service-connected disability which makes the veteran unable to procreate. The VA argued that certain infertility treatment will not "repair" or "cure," or result in "decided improvement" of the disability, so therefore cannot be provided under current VA policy. PVA believes that if this statement was consistent across all current VA policies, items such as prosthetics, orthotics and sensory aids could not be authorized, since they neither "repair" or "cure," but are rather a service to overcome the resulting effect of the disability.

From there, it follows logically that certain fertility services also help overcome specific service-connected disabilities. It seems unconscionable that the VA will provide a veteran compensation for the loss or loss of use of one or more creative organs under Section 314(K) of title 38 U.S. code, but will not afford the same veteran access to medical care to mitigate the resultant condition. If this approach was applied in all cases, the overall health care provided to veterans would be extremely limited and new procedures would seemingly never be applied. Examples are too numerous to list.

It is interesting to note that the VA, finally and inconsistently, did agree to provide fee-basis contract services for in vitro fertilization procedures for this woman veteran. However, the VA then reversed this decision by way of a general counsel's opinion that they would not, in the future, reimburse veterans for such services. In effect, what the VA is doing is forcing the Congress to give them the expressed authority in title 38 U.S. code. That is why we are here today. It is our combined duty to put an end to this inconsistency so that the VA will provide medical treatment to veterans, men and women, whose service-connected disabilities prevent or impair them from conceiving children.

PVA has more than just a two case interest into this issue. Since 1977, we have commissioned four projects in this area with a fifth project funded by

our Eastern PVA Chapter and, currently, under way at the University of Michigan. (Waring, Bennett, Ayres, "A Multidisciplinary Approach to Male Spinal Cord Injury Fertility.") To date, this project has resulted in six pregnancies. In the future, we hope to support more research in this area through PVA's Spinal Cord Research Foundation.

But more than that, our National PVA Service Officers report unfortunate examples where marriages break up because of the veteran's inability to procreate; of tales of adoption which sometimes have no end, because the pool of available adoptive children is small and still dwindling. And we hear happy stories of veterans who were lucky enough to have the ability, time and resources and who received fertility treatment and who now have the children they were often told they never would have.
Up until a few years ago, most spinal cord injured males were told two things: first, you will never walk again; second, you will never have children. Today, thanks to advancing technology for many spinal cord injured veterans, the latter just does not have to be true any more.

But such technology is useless unless the VA allows for its application. It is here that a significant gap exists. The VA's legal interpretation on its authority to provide such services is, in the opinion of PVA and others, incorrect. However, with grateful appreciation to Chairman Montgomery and his introduction of H.R.3161, by request of PVA, we now have the means to erase any doubts of the VA that may exist on this issue. H.R. 3161 is currently cosponsored by Representative Rowland of Georgia, Representative Kanjorski, Representative Evans and Representative Bilirakis. We ask for the favorable action of this Subcommittee on H.R.3161.

II. Legislative Background and Research

The Office of Technology Assessment (OTA) is currently compiling a report on infertility which, at the request of Senator Frank H. Murkowski, will include a chapter on the reproductive health of veterans. The report, now in its final draft form, is due to be released later this year or early next year. A draft version of this report finds that the actual numbers of veterans eligible for procreative services (as limited by the legislation) is quite small. The report identified approximately 15,651 male veterans under the age of 55 years and between 1,200-1,300 female veterans between the ages of 17 to 44 on the VA records with known service-connected medical conditions that could cause infertility. It is not known how many of these veterans actually are infertile. PVA believes the accurate number to be much smaller. When reduced to the number of eligible veterans who are currently married and who would actually elect and be appropriate candidates for these services, the number is smaller still.

Legislation authorizing the VA to provide procreative services was approved in the Senate (Sec. 205 of S.2422) during the 99th Congress. The provision has been reintroduced this session by Chairman Alan Cranston and has been ordered to be favorably reported out of the Committee on Veterans' Affairs (Section 2 of S.6). The measure has broad bipartisan support and is expected to pass the full Senate.

Cost
Senator Cranston, in the Congressional Record, January 6, 1987, stated, "I do not foresee significant new costs associated with this proposed change in the law. However, to the extent there are new costs associated with this new authority, it is my intention that they would be absorbed through a shift of funds from lower priority expenditures under the VA's medical care account . . . " As a result, no new appropriations would be provided in connection with the new authority." PVA believes this statement of Senator Cranston to be true and accurate, and it is the stated mission of the VA to provide priority medical care to veterans being treated for service-connected disabilities.

However, the VA testified before the Senate Committee on Veterans' Affairs, May 21, 1987, that the first year cost of Senator Cranston's provision would be $.58 million and $4.1 million over five Fiscal Years. PVA questions the accuracy of these numbers considering we do not even know the exact number of veterans to receive the services, much less what the kinds of treatment the services would entail. Fertility treatment, after all, is often as simple as determination of the fertility cycle, rather than as complex as in vitro fertilization.

It has been the experience of PVA that, in our specific veteran population, in vitro fertilization is the exception rather than the rule. Much more common is services to achieve sperm retrieval from the spinal cord injured male veteran and subsequent artificial insemination in the veteran's spouse. Neither of these procedures is either costly or complex.

It is important to note that in vitro fertilization (IVF) is a complex scientific process which requires an enormous amount of time and energy on the part of the couple. Because of this, in vitro fertilization is often attempted as a last resort. And also because it can involve specialized fertility drug administration for extended periods, careful medical monitoring, various medical procedures and extraordinary physical discomfort to the woman, in vitro fertilization is not an attractive alternative to the normal course of conception. Secondly, there are only 75 active IVF programs in the U.S. Some of these clinics are dependent upon private funding and sometimes this funding is contingent upon the actual number of attempted fertilizations and the resultant successful pregnancy rate. As a consequence, candidates are so carefully screened that only the most likely candidates actually are admitted into the program.
The specific legislation, H.R.3161, is a very carefully crafted and purposefully limited measure. The legislation authorizes services, within reasonable limits of acceptable medical standards, to achieve pregnancy in a veteran in conjunction with a veteran's spouse or, in a veteran's spouse in conjunction with a veteran, by correcting or enhancing the procreative ability of the veteran where such services are necessary to overcome a service-connected disability impairing the veteran's procreative ability. The language of the bill limits the authorization to include only those services which correct or enhance the existing procreative ability of the service-connected disabled veteran. The legislation is not intended to provide services in such cases where it is medically determined that little or no procreative ability exists (examples: bilateral oophorectomy or total abdominal hysterectomy in women, or aspermia, azoospermia and bilateral orchiectomy in men). This effectively limits the services by excluding the use of donor gametes. The question of surrogate services or services to significant others is likewise ruled out by the language which specifies that the services be provided only to the veteran or, if necessary, the veteran's spouse.

Clearly, the legislation is not intended to provide any services at the expense of the VA to correct or enhance any existing or pre-existing procreative disability in the spouse. However, the language does include such services and medical procedures for the spouse which are essential to the effective treatment of the veteran in order to achieve pregnancy (example: fertility workup and determination of ovulatory cycle in veteran's wife prior to the artificial insemination with her husband's sperm).
It is essential to note that there is precedence in title 38 with comparative authority for services to be provided for a veteran's spouse in section 601 6(B), when such services are deemed necessary for the rehabilitation of the veteran. Additionally, there is a wide range of medical services authorized for eligible dependents under CHAMPVA, the VA's medical insurance program, which provides up to 80% of the cost of medical treatment to the eligible dependents of 100% service-connected disabled veterans. The importance of this in relation to costs of the services is demonstrated by the fact that close to 90% of PVA's service-connected membership are rated 100% for their disability. Therefore, the VA is already providing for the medical treatment of their spouses, including pre and post natal care of newborn dependent children.

For those spouses who are not CHAMPVA eligible, the responsibility of the VA would terminate at the moment of conception. At this point, the veteran's spouse, or a third party payer, would be responsible for the continuation of private sector health care services and for the health care maintenance of the child. The VA is not a provider of obstetrical and pediatric care, nor do we believe that, at this point, they should be. Further, PVA believes that the most economical, viable method of providing VA fertility services should be fee-basis, contract care.

During the course of our research on this legislation, we came across the fact that Department of Defense hospitals are providing certain fertility services to active duty military personnel, their dependents and eligible military retirees. These services include complete fertility workup and assessment (male and female) fertility drug therapy and artificial insemination. They do not, however, provide in vitro fertilization or gamete intrafallopian transport (GIFT). The available services are provided without

regard to service-connected fertility disability. It is inequitable that the government will provide certain fertility services to active duty military or retirees, but not to veterans whose disability is a direct result of their military service.

Upon further research, we found that on July 1, 1985, the State of Maryland, by law, required the state Blue Cross/Blue Shield plan to provide, as a basic benefit, full coverage for in vitro fertilization and fertility services. As reported by Maryland Blue Cross/Blue Shield, their cost experience has been lower than the VA estimates, with a reported total of 650 paid claims for these procedures over the past two-year period, at a total cost of approximately $300,000 per year. More states are expected to follow suit; for example, the State of Massachusetts has available a policy rider which the participant can elect, to cover the cost of such services.

III. Ethical Consideration

PVA believes that all health care provided to veterans must be ethically sound. We strongly support H.R.3161, because it upholds the constitutional right to procreate and because the services that the legislation authorizes have been found to be medically and morally acceptable. The legislation itself is strongly profamily, an American ideal upon which our country is based.

In 1979, the Department of Health, Education and Welfare, after the formation of its Ethics Advisory Board, issued the following conclusions:
"Research involving human in vitro fertilization and embryo transfer is ethically acceptable provided that: If the research involves human in vitro fertilization without embryo transfer, these conditions must be satisfied: (a) the research complies with regulations governing research with human subjects; (b) the research is designed to establish the safety and efficacy of embryo transfer and to obtain important scientific information not reasonably attainable by other means; (c) informed consent is obtained; (d) no embryos will be sustained in vitro beyond the stage normally associated with completion of implantation (14 days after fertilization); and (e) the public is advised of possible risk. In addition, if the research involves embryo transfer following human in vitro fertilization, embryo transfer will be attempted only with gametes obtained from lawfully married couples." Although the Ethics Advisory Board no longer exists under the current Secretary of Health and Human Services and there is no research of this nature currently under way in that Department, it is important to note that when the issue was analyzed, it was found to be ethically acceptable. Additionally, PVA has no hesitation in accepting the Ethical Advisory Board's limitations on research and/or the constraints as relevant to procedural application, per the agency regulatory process, on in vitro fertilization as we believe them to be based on sound biomedical ethics.

More recently, in September of 1986, the Ethics Committee of the American Fertility Society provided a report entitled, Ethical Considerations of the New Reproductive Technologies.
The Committee is composed of nationally recognized experts in the following fields: medical law, obstetrics and gynecology, developmental biology, moral theology, endocrinology and biomedical ethics.

The Committee unanimously found that basic in vitro fertilization (described as the basic scientific procedure, but excludes donor semen, donor eggs, surrogate wombs or experimentation on the preembryo) is ethically acceptable. H.R.3161, as drafted, would also authorize basic IVF and, specifically, excludes the variants described above.

The Committee also found as unanimously acceptable artificial insemination with the husband's sperm (AIH), as authorized in H.R.3161. The reproductive technologies which the Committee found controversial (procedures involving donor gametes, surrogate motherhood, uterine lavage etc.) are specifically excluded in H.R.3161.

The procreative services authorized in H.R.3161, the vast majority of which are considered routine medical procedures and when examined against prevailing ethical consideration, are noncontroversial, ethically acceptable and safe medical treatment for veterans with service-connected procreative disabilities. It is imperative that the Committee acknowledge that the merits of this legislation far outweigh any argument against the procedures it authorizes.

In summary, ten years ago, the hope of producing offspring by a spinal cord injured male was grim. Now, with the advent of newer, improved reproductive techniques (IVF) and the increased use and acceptance of age old techniques (artificial insemination), our membership can become and certainly are becoming parents. Veterans must have access to this new technology. PVA believes that the enactment of H.R.3161 will take the VA one step further towards its goal of comprehensive, holistic, high quality health care to our nation's veterans.

This concludes my testimony on H.R.3161. I would now appreciate the opportunity to address the remaining legislation.

S.1464, as amended - VA Quality Assurance

PVA has also been asked to present its views on Title 2 of S.1464 (as amended) and ordered reported by the Senate Veterans' Affairs Committee. The bill would enhance the VA's quality assurance review and implementation procedures by augmenting and providing statutory authority, within the Office of the Chief Medical Director, for an Office of the Medical Inspector, and create an ASSOCIATE Chief Medical Director for Quality Assurance tasked to implement quality assurance recommendations. The legislation would also create, within the Office of the VA Inspector General, the position of Assistant Inspector General for Health Care Quality Assurance, to enhance the ability of that office, to provide augmented, independent review capability.

PVA has long been concerned that the VA's quality assurance procedures should be greatly upgraded and enhanced. The obvious result of such an effort would improve the ability of the VA to ensure that high standards of health care are set and maintained. The intent of this legislation can only enhance the credibility of the agency and the level of confidence placed in the VA by veterans and nonveterans alike.

PVA supports the intent of this legislation and encourages this Subcommittee, in reviewing similar legislation, to look closely at any recommendation, or combination of recommendations, which would upgrade the position and function of the VA's overall quality assurance review and implementation process.

TESTIMONY OF TIMOTHY P. CONDON
OFFICE OF TECHNOLOGY ASSESSMENT
U.S. CONGRESS
BEFORE THE SUBCOMMITTEE ON HOSPITAL AND HEALTH CARE
OF THE HOUSE COMMITTEE ON VETERANS' AFFAIRS

TREATMENT OF INFERTILITY

September 23, 1987

Thank you, Mr. Chairman, and members of the subcommittee. I am Tim Condon from the Biological Applications Program at the Office of Technology Assessment. I presently serve as an analyst for an ongoing OTA assessment of Prevention and Treatment of Infertility.

This morning I will briefly describe some the medical practices that are collectively known as infertility services, including some that have particular relevance to the reproductive health of veterans.

There are many factors that cause or contribute to infertility. Historically, infertility was thought to be a dysfunction of the female reproductive system. However, today, both male and female factors are believed to contribute equally to infertility. Since male infertility problems have not been studied as extensively as those of females, much less is currently known about the causes and treatment of infertility in males.

Causes of female infertility can be classified in at least three broad categories: 1) defects in egg production; 2) tubal defects, that is, blockage or damage in the female reproductive tract which inhibits transport of eggs or sperm; and 3) implantation problems, failure of the fertilized egg(s) to implant in the uterus.

Male infertility may be broken down into two broad categories: 1) defects in **spermatogenesis**, the production of viable sperm (and semen); and 2) defects in the **transmission** of sperm from the testes to the female reproductive tract such as in cases of impotence.

In recent years many new sophisticated technologies, such as in vitro fertilization, have been developed for the treatment of infertility. In addition to these new reproductive technologies, great progress has been made in the treatment of infertility with more traditional medical and surgical treatments such as drug therapy, artificial insemination, and reproductive tract surgery. These more traditional approaches, at present, account for the overwhelming majority of infertility treatments.

Fertility Drugs

One major cause of female infertility involves ovulation, that is, the maturation and release of the egg(s) from the ovary. In some cases, this complex process that involves the brain, the pituitary gland, and the ovaries breaks down. The result can be failure in egg development and egg release from the ovary and absence or irregularity of menstrual cycles. To correct this condition a number of therapeutic agents are used. The most commonly employed are those compounds known as fertility drugs. These drugs work to mimic, enhance, or augment the natural hormonal state thus stimulating egg production (often multiple eggs) and egg release. In some patients egg production and fertilization can appear normal but the lining of the uterus fails to develop properly to allow implantation of the embryo. Administering progesterone, the hormone that normally prepares the uterus for implantation, can often facilitate implantation.

Although these therapies are highly effective treatments for female infertility, the efficacy of drug and hormonal therapies in the majority of male infertility patients remains unclear and are not commonly practiced.

Surgical Treatments

Surgical treatment of the reproductive tract remains a popular approach to some infertility problems for both male and female infertility. Although there are many different surgical procedures, I will mention only a few here.

Obstructions in the reproductive tracts, caused by infections, previous surgery, or failure for proper development, are a frequent cause of infertility in males and females. In the female, these obstructions can block the movement of eggs from the ovaries to other parts of the reproductive tract where fertilization would normally take place. In the male, obstructions of the male ducts can prevent release of sperm during ejaculation. Surgical correction for these problems can frequently be accomplished by the skilled surgeon. With the aid of a microscope, fine surgical instruments, and much practice, the microsurgeon can locate and remove the damaged portion of the tube. The two ends of the tubes are then cleared of any material and the insides of the tube are joined and sutured together. These microsurgical techniques have improved with the increased requests for reversal of tubal ligation and vasectomies.

Antibodies

In some cases of infertility the immune system of the female or male partner will produce antibodies against sperm or the various components of semen. These antibodies, if present in the male, will decrease the quality and viability of sperm. If present in the female reproductive tract, they can inhibit sperm transport and the interaction of sperm

and egg. Treatment for this condition can be difficult. In some cases hormone therapy will suppress the production of these antibodies by the immune system. If reduction of antibodies is not accomplished, in vitro fertilization, artificial insemination with the husband's sperm, donor insemination, and gamete intrafallopian transfer may be appropriate treatments to circumvent the condition. I will describe some of these treatments momentarily.

In Vitro Fertilization and Embryo Transfer (IVF/ET)

In vitro fertilization and embryo transfer (IVF/ET) is a highly sophisticated infertility treatment. This treatment involves obtaining mature eggs through surgical procedures such as laparoscopy or through nonsurgical means such as ultrasound guided egg-retrieval. These mature eggs are produced by natural ovulatory cycles, or more commonly, by ovulation induction with fertility drugs. Once the eggs are collected, their maturity is assessed microscopically, and fertilization of mature eggs is attempted with sperm. If available, approximately 50,000 motile sperm for each egg are added to the culture dish to achieve fertilization. The sperm and eggs are incubated for about 18 hours. Eggs are then examined to see if fertilization has occurred. The fertilized eggs then divide, usually within 35 hours after insemination, and the resulting embryos are transferred back to the uterine cavity. If the embryo implants in the uterus, small increases in human chorionic gonadotropin, the pregnancy hormone, can be measured in blood and urine. Other new techniques that have been developed to treat infertility include gamete intrafallopian transfer (GIFT), tubal ovum transfer, and embryo flushing.

Artificial Insemination

Artificial insemination (AI) is one of the oldest forms of infertility treatment, having been performed in the eighteenth century. Even though more sophisticated infertility treatment techniques have been developed since these early reports, AI continues to be one of the simplest and most successful infertility procedures.

The practice of AI is usually classified as using the husband's sperm for insemination (AIH) or using donor sperm (AID). In each one of these situations the sperm can be placed within the cervical canal, or directly into the uterine cavity. All inseminations are performed around the time of either drug-induced or natural ovulation.

Intracervical insemination involves placing sperm in or near the cervical canal of the female reproductive tract by means of a syringe or catheter (other items may also be used for AI). Practices vary among infertility programs; however, multiple inseminations during each fertile period are usually performed to increase the likelihood of conception. The optimum time for insemination is the period just prior to, or during ovulation. The female reproductive tract is most receptive to sperm at this time. Approximately 48 hours before the expected ovulation, sperm are collected from the husband or donor into a clean, sterile container. Usually, within 1 to 2 hours after collection, the semen sample is loaded into a syringe with a flexible tip and placed in the cervix. Similar procedures are employed when frozen donor sperm are used.

Intrauterine insemination differs from intracervical by the location of sperm deposition in the female reproductive tract. In instances where cervical mucus is hostile to sperm, such as when antibodies to sperm are present in the female reproductive tract, it is often advantageous to bypass the cervix and place sperm directly in the uterine cavity.

Special Veterans Consideration

The outlook for fertility in paraplegic men after spinal cord injury is unfortunately poor; the outlook for paraplegic women is often better. However, techniques such as artificial insemination and in vitro fertilization can be useful to treat these patients. Men with spinal cord injuries often (but not always) suffer from impotence because of neurological deficits in the spinal cord and may have sperm of poor quality. If the testes are producing sperm and testosterone, the major problem with reproducing becomes transmission of sperm to the female reproductive tract. One treatment, electroejaculation, involves the electrical stimulation of the nerve complex that controls ejaculation. By using this stimulation, semen samples can often be obtained from these patients. Sperm may also be obtained from the male reproductive tract by means of direct puncture and removal. Although sperm collected from spinal cord injury patients may be decreased in number and quality, there may be a sufficient quantity to achieve pregnancy by medically assisted means such as artificial insemination or in vitro fertilization. A number of births have been reported using these approaches. In addition, we are aware of several VA facilities that are conducting research on the use of electroejaculation and vibration-induced ejaculation to treat sexual dysfunction and the resulting infertility of paralyzed veterans.

Sexual dysfunction as a cause or contributing factor of infertility may be present in as many as 5 percent of infertile couples. In the male, these conditions usually fall into one of three categories; impotence, which can have psychological or organic causes; premature ejaculation, which, if severe, causes failure of sperm transmission to the female reproductive tract; and retrograde ejaculation, where semen is propelled into the bladder rather than out through the penis. Because these forms of sexual dysfunction also interfere with the transmission of sperm to the female reproductive tract, these

patients suffer from infertility. Patients with organic or physical impotence may respond to hormone therapy, surgery to restore blood flow to the penis, or drug therapy that directly induces erections. In addition, erection and ejaculation may be induced by electrical or vibratory stimulation such as are used in spinal cord injury patients. Psychogenic impotence and premature ejaculation can be successfully treated with psychotherapy and behavior modification. Retrograde ejaculation can be treated with drugs or surgery depending on the etiology of the condition. However, these treatments often produce variable results making this course of treatment difficult to assess. Sexual dysfunction in the female can also affect reproduction, although negative consequences of these disorders on fertility are not as common.

Summary and Conclusions

In summary, there are a variety of traditional and more recently developed medical and surgical treatments for infertility. Treatments often involve both members of a couple, each of whom may have a condition that causes subfertility. Medical treatment can range from instruction of the couple in the relatively simple methods of pinpointing ovulation to more complex treatments involving ovulation induction with potent fertility drugs and artificial insemination. Surgical treatments also span a wide spectrum of complexity, from ligation of testicular varicose veins to delicate microsurgical repair of reproductive tract structures in males and females.

Although new reproductive technologies offer great promise for many infertility patients who could not otherwise be successfully treated, new discoveries and improvements of more traditional infertility treatments such as ovulation induction, microsurgery, and artificial insemination, continue to make these treatments the most widespread and successful approaches. It is also important to note that even complex and sophisticated treatment of one partner will be of no benefit if the other partner suffers from undiagnosed infertility. Therefore, unlike most other areas of medical treatment, the couple as a unit is properly considered to be the infertility patient.

Even as infertility treatments become more sophisticated and complex, basic knowledge of the male and female reproductive process remains lacking. Further research and development are essential in order for dramatic improvements in infertility treatment to occur.

Mr. Chairman, I am pleased to answer any questions you may have.

Statement of

The American Legion

1608 K STREET, N. W.
WASHINGTON, D. C. 20006

by

E. PHILIP RIGGIN, DIRECTOR
NATIONAL LEGISLATIVE COMMISSION
THE AMERICAN LEGION

and

ROBERT E. LYNGH, DIRECTOR
NATIONAL VETERANS AFFAIRS & REHABILITATION COMMISSION
THE AMERICAN LEGION

before the

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

on

CREATION OF VA MEDICAL CARE INSPECTION UNITS

September 23, 1987

Mr. Chairman and Members of the Subcommittee:

The American Legion is pleased to have this opportunity to present its views on a measure the Subcommittee has for consideration, Title II of S. 1464.

S. 1464 -- Title II

We shall now proceed to offer comment on Title II of S. 1464, which has been favorably reported by the Senate Committee on Veterans Affairs.

Title II of the bill deals with quality assurance and independent inspections within the VA and as they relate to veterans health care. The American Legion does have some definite views on these important subjects.

Sections 201-204 of the title would upgrade VA medical investigation, quality assurance, and medical risk-management programs and operations by: 1) establishing an effective, expanded, and autonomous office of the Medical Inspector General (MIG), directly accountable to the Chief Medical Director (CMD), with adequate support positions, responsible for investigating reports of inadequate quality of care; 2) establishing the position of Assistant Chief Medical Director for Quality Assurance; and, 3) establishing within the VA's Office of Inspector General (IG) an Assistant Inspector General for Health Care Quality Review, and support positions, responsible for comprehensive monitoring of the functioning of the MIG's operation as well as of the DM&S quality assurance and risk management programs.

Mr. Chairman, it seems that these measures being considered are a direct result of reports issued earlier this year by the House Committee on Government Operations and by the General Accounting Office, both of which question the reliability of the quality assurance programs within the VA, at both the station level and from Central Office.

May we say at this point that we have made staff studies of both reports. Through the work of our Field Service, which conducts regularly scheduled surveys of VA health care facilities, and reports we receive from our Service Officers and from our volunteers working in VA Medical Centers and Clinics, we believe we have a reasonably good basis of information regarding the operation of the VA's Department of Medicine and Surgery. We stipulate that our information does in fact come to us from non-professional sources, and we do not pretend to be able to evaluate the quality of care provided to veteran-patients by the professional care-givers in DM&S. However, our experience has been that if a breakdown of care delivery occurs, we usually know about it. So we believe we can speak to this subject with some measure of credibility.

With that in mind, we would like to say first that the reports mentioned earlier do have some substance and merit. We also are aware that VA has responded to both reports, agreeing in some measures and disagreeing in others. We believe the VA response also is a valid one. The point being that the VA system is so vast and so complex that it is inevitable that problems will arise. Some may be systemic while others pertain to isolated incidents.

We believe the VA is making a good faith effort to improve both care-delivery and quality assurance. We believe the methodology for reporting accident and incidents needs to be improved at the station level, to insure that serious incidents do not escape the notice of Central Office so that appropriate action can be taken when indicated.

We would not deny an understandable reflex by station management to protect its staff as much as possible, while stopping short of blatant attempts to cover up acts of malfeasance or non-feasance, or malpractice. We believe it must be agreed that the dividing line in many instance is narrowly drawn and some omissions of reporting can possibly be excused for that reason. It is also true, however, that whenever a question arises then the incident should be reported without fail.

The agreed objective is to have a thorough and reliable reporting system, and a method in place and functioning that would guarantee appropriate action in the face of any instances of malfeasance, non-feasance or malpractice. With those goals in mind, The American Legion does support establishment of a Medical Inspector General and a new position of ACMD for Quality Assurance, with Congressionally mandated staff support to guarantee their effective functioning.

We have two reservations, however, related to the mechanism about the Medical IG's requirement to report to the Chief Medical Director. While we know the medical community would not likely agree with us, we would ask the Subcommittee to give serious consideration to the advisability of attaching the Medical IG directly to the office of the Administrator, as is now the case with the VA Inspector General. This proposal would have the Medical iG reporting only to the Administrator with complete authority to select matters for medical investigation.

The reason for this suggestion is that the appearance of complete independence from DM&S control is essential to establish the Medical IG's credibility with veteran-patients, with service organizations as consumers' representatives, and with outside observers who regularly monitor and occasionally report on VA medical practices. We believe that requiring this new inspection unit to report to the Chief Medical Director could leave open the continuing possibility of having to defend its independence and

objectivity in accomplishing its work. Having to regularly defend its objectivity would likely compromise most or all of the Medical IG's credibility. Under such circumstances, we fear that the full potential of the Medical IG would not be achieved.

Secondly, we ask the Subcommittee to carefully examine the advisability or necessity to establish a new position of Assistant Inspector General for Health Care Quality Review in addition to creating the Medical IG's position. In our opinion, establishing both would produce a redundant layer of inspection activities. This would be particularly the case if, as we suggest, a Medical IG is assigned to the Office of the Administrator.

With these adjustments, The American Legion is wholeheartedly in favor of actions that would enhance the VA's ability to assure quality review in its health care program. With reference again to a new position of ACMD for Quality Assurance, we blieve that proposal to be an excellent one, with the caveat that it can only succeed if it is provided with sufficient staff to enable it to execute its mission.

Mr. Chairman, that completes our observations in this pending legislation, and we again thank the Subcommittee for the opportunity to be heard.

STATEMENT OF
DAVID W. GORMAN
ASSISTANT NATIONAL LEGISLATIVE DIRECTOR
FOR MEDICAL AFFAIRS
DISABLED AMERICAN VETERANS
BEFORE THE
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE
HOUSE VETERANS AFFAIRS COMMITTEE
SEPTEMBER 23, 1987

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

On behalf of the more than one million members of the Disabled American Veterans and it Ladies' Auxiliary, I am pleased to have the opportunity to appear here today and present our views on legislation relating to the Veterans Administration's health care system.

Mr. Chairman, our views have been requested on H. R. 3161, a bill to authorize certain additional medical services for veterans with service-connected disabilities; and draft legislation to establish a Medical Inspector General within the Veterans Administration.

H. R. 3161

Introduced by yourself, Mr. Chairman, H. R. 3161 would, via amendment to Section 612 of Title 38, United States Code, add a new Subsection authorizing the Administrator to provide certain medical services to a veteran (and, if necessary, a veteran's spouse) to the reasonable extent necessary to overcome the effects of a service-connected disability which prevents or impairs the ability of conceiving a child.

While the DAV has no official position to the perceived intent of this measure, we feel explanatory report language is required to express the limitations of this bill.

Our interpretation is that services would be provided to "...achieve pregnancy..." (emphasis added). Therefore, we do not envision the VA to be required to provide obstetric services, prenatal or postnatal care in conjunction with any successfully achieved pregnancy. We would also raise the issue of the Agency's potential liability relating to possible complications and/or permanent disability to the mother or possible birth defects affecting the child.

Until these questions are fully addressed, the DAV is compelled to withhold its support of this measure.

DRAFT LEGISLATION

As we understand it, Mr. Chairman, draft legislation is being proposed with the intent to strengthen and expand the VA's role of ensuring that quality medical care is being provided to veterans by the VA's Department of Medicine and Surgery (DM&S).

Mr. Chairman, in our view, the issue of quality assurance is a vital one and of tantamount importance to the credibility and continued existence of the VA's health care system.

As you are aware, Mr. Chairman, legislation has been introduced -- S. 1464 -- that addresses this issue in varied detail. For the purpose of our discussion of this issue, S. 1464 will be used as a reference point.

MEDICAL INSPECTOR GENERAL

During September, 1980 the Office of Medical Inspector -- as we recognize it today -- was administratively established within the Department of Medicine and Surgery.

The Medical Inspector -- who currently reports to the Deputy Chief Medical Director -- provides staff support to the Chief Medical Director to assure optimal quality care. Management support and quality assurance activities involve coordinated working relationships, internal and external to DM&S. The Medical Inspector is responsible for monitoring, investigating and reviewing required reports of incidents involving veterans treated in VA medical care facilities.

Issues identified as requiring corrective action are to be implemented by the Regional Directors, including disciplinary actions concerning employee performance; clinical competence; and meeting acceptable standards of medical care program changes or management activities.

In conjunction with the VA Inspector General's (IG) overall responsibilities, the Office of Inspector General (OIG) provides oversight for the quality of care medical investigations conducted by both the Medical Inspector and DM&S field stations. This oversight responsibility involves the review of completed DM&S quality of care case files as well as, when necessary, on-site review.

As you may know, Mr. Chairman, the General Accounting Office (GAO) has released two reports of recent date -- June 1985 and May 1987 -- both relating to the VA's quality assurance programs. Both reports identified rather major failures on the part of the VA, the Department of Medicine and Surgery and the Medical Inspector to provide adequate oversight and supervision of portions of the VA's quality assurance endeavors.

The results of the GAO effort has opened the door to an argument regarding the degree of quality assurance (QA) within the agency. Some argue that the VA's QA efforts are being portrayed as grossly ineffective while others argue that the issue of QA standards and efforts were not actually being called into question.

While we are uncertain as to the correctness of either position, we are extremely concerned that the intent of the function of the Medical Inspector is certainly being placed in a tenuous position.

Mr. Chairman, as we understand it, the Office of the Medical Inspector consists of two professional staff and two support staff. This limited staffing may very well be the underlying reason for what is obviously a serious lack of effectiveness of this vital DM&S function.

Mr. Chairman, the provisions of the senate bill -- S. 1464 -- which intends to provide the foundation to resolve this vital service include:

* statutorily establish the Office of Medical Inspector General in the Office of the Chief Medical Director (CMD) and make the head of that office directly accountable to the CMD;

* require the Medical Inspector General to be a physician who would be appointed by the Administrator, upon the recommendation of the CMD for a term of four years, removable only for cause;

* require the Office of the Medical Inspector General to be staffed by not less than five full time physicians, two registered nurses, one dentist and five support personnel.

* require the Administrator to transfer to the Medical Inspector General ten staff years, and such funds as are designated by the CMD to be necessary to support those positions;

* except for those instances where the Administrator or the CMD specifically requests an investigation, give the Medical Inspector General sole discretion as to which investigations to conduct;

* require that all Medical Inspector General investigations conducted by personnel from outside the medical facility being investigated include at least one Central Office professional Medical Inspector General staff member;

* require the Medical Inspector General to be a member of all policy making bodies of DM&S relating to the quality of care and quality assurance programs;

* require the CMD to take appropriate steps to assure that all DM&S employees understand their responsibilities for quality assurance activities and are advised that failure to cooperate with such activities, or report activities as required by VA regulations or manuals, will result in appropriate disciplinary action; and

* require the Medical Inspector General to make annual reports to the Chief Medical Director, the Administrator and the House and Senate Veterans Affairs Committees.

ASSISTANT CHIEF MEDICAL DIRECTOR (ACMD)
FOR QUALITY ASSURANCE

During March 1985, the Office of Quality Assurance (QA) was established within the Department of Medicine and Surgery. Since that time all QA activities and programs are the responsibility of that office except patient injury reporting responsibility for which remains with the Medical Inspector.

S. 1464 proposes the statutory creation of an ACMD for quality assurance within the Department of Medicine and Surgery (DM&S) via appropriate amendment to Section 4103(a)(4) Title 38, United States Code.

Mr. Chairman, it is our view, as previously stated, that an effective and meaningful QA program must exist within DM&S if the Chief Medical Director is to meet his mission of providing quality health care services to disabled veterans.

We feel that the highest degree of emphasis must be directed to the QA program. While we are not necessarily convinced that a change of title only for the responsible activity will produce the desired results, we are of the firm opinion that an effective QA program should be the cornerstone for the VA's health care system. If, in the wisdom of this Subcommittee, the most effective method to realize this goal is the creation of an ACMD for quality assurance, the DAV would have no objection.

ASSISTANT INSPECTOR GENERAL
FOR HEALTH CARE QUALITY ASSURANCE

Mr. Chairman, the final provision of the quality assurance (QA) question relates to the statutory creation of an Assistant

Inspector General for Quality Assurance Health Care Review within the VA's Office of Inspector General (OIG).

In our view, the intent of such a proposal is meritorious and should be seriously considered by the Subcommittee.

The VA Inspector General, in accordance with the Inspector General Act of 1978 (Public Law 95-452), directs an independent and objective organization whose purpose is to plan, organize, staff, direct, control, and report on audits and investigations of VA programs and operations; to recommend policies for the purpose of promoting economy, efficiency, effectiveness, preventing and detecting fraud, waste, and abuse in VA programs and operations; to ensure that the Administrator and Congress are kept fully informed about problems and deficiencies throughout the agency and the necessity for corrective actions; and to provide leadership and coordination on complex audit and investigative matters. An integral part of this charge is oversight of the Department of Medicine and Surgery.

As we understand it, the Office of Inspector General is responsible for performing oversight reviews of all quality of care medical investigations and surveillances undertaken by the Medical Inspector of the VA's Department of Medicine and Surgery (DM&S).

An effective oversight program is critical to assuring the quality and independence of the DM&S Medical Inspector. Lacking adequate in-house medical expertise, the IG attempts to use a common sense approach when making evaluations and determinations of the sufficiency of the Medical Inspector's activities. An obvious problem with this approach is that the IG cannot fully evaluate issues of a purely medical nature and be able to state with any degree of credibility that the Medical Inspector's findings and actions are or are not appropriate. In this regard, the IG must and does rely heavily on the expertise and integrity of the Medical Inspector and his staff. Utilizing this limited approach to the evaluation of the Medical Inspector's activities, it appears reasonable that the IG sometimes may be faced with challenging the medical opinions and positions taken by the Medical Inspector.

Mr. Chairman, we have long been concerned -- and have related our concerns -- with the scope and certain specific findings identified in numerous IG audits of various VA medical centers.

For example, it is not uncommon for the IG to conclude and recommend during their cyclical audit process of medical centers that:

* veterans' inpatient length of stays could be reduced;

* veterans' transfer/discharge from a period of hospitalization was not timely;

* veterans should be placed in more appropriate care environments;

* veterans' admissions to the hospital were not warranted;

* veterans should be treated on an outpatient versus an inpatient basis for their conditions;

* veterans' surgical needs could be better performed on an outpatient or ambulatory surgery basis;

* reduction of employees should occur within certain hospital sections or services;

* dental treatment practices should be revised; and

* construction projects should be revised or cancelled.

Mr. Chairman, issues such as related above most obviously have a direct relationship and impact on how medicine is being practiced in the VA health care system and how medical services are being furnished to disabled veterans.

Inherent in the audit process and ultimate decision and policy making process is the important and vital element of medical knowledge and considerations.

It would seem only reasonable to conclude that quite often the OIG and the Medical Inspector and/or the Department of Medicine and Surgery may disagree on certain issues and points. Situations such as these have raised considerable concerns which have not been adequately addressed by the VA.

For example, how are such disagreements ultimately resolved?

Currently, the OIG is without individuals on his staff with the necessary medical expertise to adequately address such patient care issues. Therefore, it seems that he must rely on the Medical Inspector and the Department of Medicine and Surgery to help resolve these questions.

In our view, Mr. Chairman, these types of questions and situations are of vital importance to the mission of DM&S to provide quality health care services. There must exist a viable and objective mechanism to resolve these questions to the satisfaction of all interested parties. This is not currently the case.

In the eyes of many there is a lack of credible, objective overview concerning the VA's health care program. Whatever oversight and investigations that are done of DM&S is done by DM&S. Therefore, we hear of a perceived "fox guarding the hen house" situation.

Perceptually, this is an unhealthy situation and perception, accurate or not, by the many observers and the stockholders of the VA system is critical.

Mr. Chairman, we have attempted to relate our views regarding the important, albeit complex, issue of quality assurance. Conceptually, we feel the provisions of S. 1464 to be valid and certainly needed at this time. Obviously, the DAV is willing and eager to work with you and your staff as well as the Senate Committee on Veterans Affairs in developing agreeable mechanisms to achieve appropriate and meaningful quality assurance measures thus ensuring objectivity to the many significant health care issues facing the VA.

We feel the requirement that the proposed Medical Inspector General and Assistant Inspector General for Health Care Quality Review should be medical doctors is valid and needed. Additionally, we feel strongly that whatever process is ultimately put in place to deal with these issues requires adequate funding and sufficient staffing levels which will be vital in any organizational success.

It is the DAV's belief that the VA health care system does, in fact, provide quality health care to those eligible veterans who utilize the system for their health care needs. However, absent an objective and highly effective quality assurance program, the VA remains vulnerable to critics of the system.

Time has shown that the VA, as a health care system, is certainly cost-effective in the provision of medical care. Certainly, it is a viable national resource. If any one issue is capable of diminishing or dismantling the system, it is the quality of health care provided. Without quality care, measured and documented by a program of quality assurance, any health care system's demise is an eventuality.

In our view, whatever direction is taken by Congress and the VA regarding this issue, it is of utmost necessity that firm delineation of required staffing requirements be established and sufficient funding levels be provided. Absent this, the program, in whatever form it emerges is doomed to failure.

Mr. Chairman, this concludes my testimony and once again, I am deeply appreciative of the opportunity to relative our views regarding this most vital issue.

STATEMENT OF

DENNIS M. CULLINAN, ASSISTANT DIRECTOR
NATIONAL LEGISLATIVE SERVICE
VETERANS OF FOREIGN WARS OF THE UNITED STATES

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

WITH RESPECT TO

CONFIDENTIALITY OF VA MEDICAL RECORDS AND HEALTH CARE LEGISLATION

WASHINGTON, D. C. SEPTEMBER 23, 1987

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

Thank you for this opportunity to present the views of the Veterans of Foreign Wars of the United States with respect to several pieces of legislation affecting veterans' health care programs. The VFW wishes to thank the Chairman and the members of the Subcommittee for holding this hearing and including our organization in the on-going process of refining and improving health care services afforded to this nation's veterans.

The first bill under consideration today is H.R. 3161, a bill introduced by request by the Chairman of the Veterans Affairs Committee, G. V. "Sonny" Montgomery, which would amend title 38 to authorize certain additional medical services for veterans with service-connected disabilities. More specifically, the Administrator of Veterans Affairs would be authorized to provide medical services to a veteran (and, if necessary, a veteran's spouse) to overcome the effects of a service-connected disability of the veteran which prevents or impairs the ability of the veteran and the veteran's spouse from conceiving a child. This bill enjoys the strong support of the Veterans of Foreign Wars. The VFW feels that such a program is long overdue, we welcome its implementation by the VA both through its own facilities and, as necessary, on a contractual basis with the private sector. There can be no doubt that such an impairment has strongly detrimental social and psychological consequences for such an afflicted veteran.

The last proposal under consideration today is title II of S. 1464, as amended, concerning the need to improve oversight of the VA Quality Assurance Program. This proposal would establish in the office of the Chief Medical Director (CMD) an Office of Medical Inspector General. This Office would be headed by the Medical Inspector General who would be directly responsible to the CMD for such functions as may be assigned to him in regulations prescribed by the Chief Medical Director. In general, the Medical Inspector General would monitor, review and investigate any adverse incident which is experienced by a patient during the course of the patient's care in a Veterans Administration health care facility, including any incident that would not normally be considered a natural consequence of the patient's disease process or illness.

The Medical Inspector General would also conduct reviews and investigations deemed necessary to identify problems in the provision of health care to veterans, and when problems are detected would propose to the CMD appropriate corrective measures. Furthermore, this position would conduct other studies, reviews and investigations relating to the quality of health care provided to veterans at the request of the Administrator or Chief Medical Director. The Medical Inspector General would also have sole discretion in determining whether to investigate any incident involving patient care or to study or review any problem in the provision of health care to veterans, with the exception that he would be mandated to conduct inquiries as directed by the Administrator or the CMD.

Section 202 of title II of S. 1464 creates an Assistant Chief Medical Director for quality assurance who would also be a qualified physician and who would be responsible to the Chief Medical Director for carrying out the responsibilities assigned by the CMD. The position would be responsible for monitoring through reviews of Veterans Administration health care facilities the establishment and implementation of health care quality assurance and risk management programs of the Department of Medicine and Surgery. Furthermore, the position would also be tasked

with monitoring the activities of the Medical Inspector General to include recommending that the Medical Inspector General conduct investigations.

The VFW is highly concerned with the need to improve oversight of the VA Quality Assurance Program. Furthermore, we very much concur with the assertion that if veterans, the Congress and the American people are to maintain confidence in the VA health care system, we must be assured that the VA is delivering high quality health care services. However, we would point out that the VA currently has in place the Office of Quality Assurance and the Office of Medical Inspector--both serving in a "watchdog" capacity within the Department of Medicine and Surgery. While the VFW has had occasion in the past to be critical of the Office of the Medical Inspector, we believe the problems that exist can be rectified. Of major concern is the current lack of adequate staffing in the Office of Medical Inspector.

We are of the opinion the provision of additional funding to provide increased staff will enhance the capability of the Office to properly implement its mandated role. We also believe that the Medical Inspector General should have greater latitude to contract for top quality medical experts who would be able to assist the Office in specific situations through the utilization of their unbiased judgment and medical expertise. While the Medical Inspector does now have this authority, it should be both expanded and utilized.

We are also of the opinion that the Office of Quality Assurance must be improved. However, in light of the fact this Office is relatively new, we believe that a greater investment of time and attention should first be made to enable it to prove its worth.

For these reasons, the VFW believes, for the time being, the VA should turn its attention and resources to improving its present capabilities rather than creating another position. Should improvements in this most critical area not materialize in the very near future, however, we would support more drastic remedial action such as that which is now under consideration here today.

Mr. Chairman, this concludes my statement, once again I wish to thank you on behalf of the membership of the Veterans of Foreign Wars for having invited our participation at today's hearing. Thank you. Germane resolution is appended to this testimony.

STATEMENT

OF THE

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Before The

Subcommittee on Hospitals and Health Care

Committee on Veterans Administration

U.S. House of Representatives

With Respect to

Veterans Administration Medical Research

September 24, 1987

Association of American Medical Colleges / One Dupont Circle, N.W. / Washington, D.C. 20036 / (202) 828-0490

Mr. Chairman and Members of the Subcommittee:

The Association of American Medical Colleges (AAMC) appreciates having the opportunity to present its views on the Veterans Administration (VA) research programs. The AAMC serves as the national voice for our nation's 127 medical schools and their students, 435 major teaching hospitals, and 85 academic and professional societies with membership engaged in patient care, research and education.

The AAMC is in a unique position to comment on the importance, not only to our nation's veterans but to our overall medical research enterprise, of VA-sponsored and conducted research. The ties between AAMC-member institutions and the VA have been and continue to be strong; currently, there are affiliation agreements in operation between 101 medical schools and 133 VA medical centers (VAMC). The affiliated medical schools have responsibility for conducting the residency training programs for VA physicians; as such, the majority of the professional medical staff at the VAMC are also faculty members at the affiliated medical school. Medical schools view the current relationship with the VA as a mutually beneficial endeavor: the VA gains a recruitment tool through the attraction of the academic atmosphere at the medical school, and the medical school gains access to valuable resources at the VA which further its academic missions. In a sybiotic relationship, the two entities conduct vital research programs and provide medical care which is of specific importance to the veteran population. Given the broad diversity of conditions prevalent among VA patients the results of VA research also have considerable relevance to the population at large. Thus, the VA/medical school partnership provides a setting where academic excellence can flourish, vital and necessary research can be conducted, and superb patient care can be delivered.

The AAMC believes that the research conducted and supported by the VA forms the third leg, along with medical care and education, of the VA's triadic effort to improve and maintain the quality of health care provided to our veterans. The reputation of VA research is well-established in the fields of biomedical, behavioral, rehabilitation, and health-services research, producing a number of Nobel laureates and award-winning scientific breakthroughs. In addition, the nature of VA research requires it to coordinate clinical research on large numbers of patients at multiple sites; the results of this type of investigation have made numerous contributions to the evaluation of new treatment approaches and delivery modalities.

In short, the story of VA research is one of stellar achievement: the antibiotic cure for tuberculosis; the modern treatment of hypertension; the first cardiac pacemaker; the lightweight, mobile wheelchair; and, the first liver transplant. While the research that produced these results was undertaken with the needs of the veteran in mind, thousands of individuals outside of the veterans population have lived better lives as the result of this and other VA-supported research.

Surely, one of the reasons the VA research enterprise has achieved the status it has is its rigorous peer-review system. Conducted by teams of scientists from academic settings mostly outside of the VA, the peer-review system assures the VA that its research dollars are buying the very best scientific investigation. In addition, merit review boards composed of academic scientists who work at the cutting edge in their respective research fields, provide the VA research enterprise with expertise on the most contemporary work in a given area under consideration for research funding. This system of evaluation has assured that VA sponsored research is of first quality, and placed it squarely in the mainstream of modern scientific research.

An additional factor in the success of VA research lies in the intergration of research and patient care. The unique clincian-based investigators that constitute VA research personnel give VA medical research a strong clinical emphasis, which contributes directly to the VA's primary mission of providing the highest quality care to the nation's veterans. Although in most cases the road from basic research to bedside treatment can be long, the emphasis at the VA on combining research and patient care is of clear and immediate benefit to the specialized population of veterans.

In conclusion, the AAMC sees the rather short history of research at the VA as a great success. The Association is proud to work in partnership with the VA in undertaking projects that contribute to the overall advancement of medical science. The AAMC is confident that resources will be provided that will allow the VA to continue to be a major component of our nation's research enterprise.

PARALYZED VETERANS
OF AMERICA

Forty Years of Service
1947–1987

October 8, 1987

The Honorable Chris Smith
422 Cannon House Office Building
Washington, D.C. 20515

Dear Representative Smith:

PVA respectfully submits the answers to your questions for the record as a followup to the Subcommittee on Hospitals and Health Care hearing on September 23, 1987.

Thank you for your interest in the views of Paralyzed Veterans of America and your work on behalf of our nation's veterans.

Sincerely yours,

Gordon H. Mansfield
Associate Executive Director of
Government Relations

GHM/kr

Attachment

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSE

CONGRESSMAN SMITH TO PVA

QUESTION #1: You state in your testimony that the Department of Defense (DOD) provides certain fertility services to active duty military personnel, but they do not provide services for in vitro fertilization. Are you aware of the reason that they do not provide this service?

ANSWER: It is our understanding that although the Department of Health, Education and Welfare Ethics Advisory Board found in vitro fertilization to be ethically acceptable, they voted against the federal funding for research involvement in that area. As a result, Department of Defense Hospitals are precluded from providing in vitro fertilization through absence of funding and authorization. It is very expensive to set up and maintain in vitro fertilization clinics which is why PVA believes it to be more cost-effective for the VA to provide fee-basis, contract services. There is, to our knowledge, no available data on needs assessment of this service that would make it cost-effective to provide in vitro fertilization to the beneficiaries of the Department of Defense health care services.

QUESTION #2: According to your testimony, in 1979, the Department of Health, Education, and Welfare Ethics Advisory Board recommended that: "in the case of in vitro fertilization without embryo transfer, the public is advised of possible risk." Do you know what "risks" the Board was referring to?

ANSWER: To the best of PVA's knowledge, the Ethics Advisory Board, in recommending that the public be advised of possible risk with regard to fertilization without embryo transfer, refers to the notion of informed consent which is essential to all research. It is important to note that the EAB was referring to in vitro fertilization without embryo transfer which is not authorized by H.R. 3161, a bill in which the specific purpose is to achieve pregnancy. However, in response to your question, PVA surmises that the specific risks of research without embryo transfer involve risks to the health of the mother, embryo loss and disposition and other risks associated with experimental procedures. It is also important to keep in mind that while this report was compiled approximately eight years ago, substantial progress has been made in devising more ethically acceptable standards for in vitro fertilization procedures. H.R. 3161 does not authorize experimental research of any kind. According to the EAB, the risks to the ovum donor (mother) in in vitro fertilization with embryo transfer are "considered to be comparable to the risks faced by female infertility patients, in general, and by women who undergo surgery for the correction of blocked fallopian tubes, in particular."

PVA has no difficulty in supporting strict federal regulations promulgated by H.R. 3161 to further restrict the intent of the law, to encompass the embryo transfer of all fertilized ovum and to forbid experimentation of any nature.

QUESTION #3: You pointed out in your testimony that the VA's medical insurance program, CHAMPVA, provides up to 80% of the cost of medical treatment to eligible dependents of 100% service-connected disabled veterans. Are procreative benefits provided under CHAMPVA? If so, is in vitro fertilization included?

ANSWER: CHAMPVA, the VA's medical insurance program does not provide procreative benefits to eligible beneficiaries because according to the VA, most of these procedures are elective if surgical in nature. CHAMPVA is not authorized to provide fertility treatment e.g. (in vitro fertilization, artificial insemination, etc.). CHAMPVA does however, provide full gynecological and obstetrical care other than annual routine gynecological examination.

The reason a discussion of CHAMPVA was included in our testimony was to demonstrate that in many cases of veterans who would be eligible for procreative services, their spouses are already beneficiaries of VA medical care. For the most part, this renders the argument that the VA should not provide medical services to non-veteran spouses invalid.

As a recent example, a 100% service-connected PVA member and his wife approached the VA for fertility services. Since the wife was enrolled in CHAMPVA, the VA was responsible for 80% of all associated medical costs including pre and post natal care of their newborn infants (this couple had twins). In fact, the only costs the VA would not cover (according to the veteran) were approximately $2000 - $3000 in bills to cover the actual artificial insemination procedures. The veteran and his wife were also responsible for the couple's 20% copayment (80% payed by CHAMPVA).

If the VA were authorized to cover the costs of artificial insemination, the out of pocket medical expenses of this veteran would be considerably less. In effect, this veteran is required to pay for such medical services necessary to overcome his procreative disability incurred while in service to the nation. To our knowledge , loss of, or loss of use of one or more creative organs is the only disability rated in title 38, U.S. Code for which compensation is payable but medical services are not authorized. PVA believes this to be inequitable.

Congressman Smith to Office of Technology Assessment

Regarding the September 23, 1987 Hearing on HR 3161 to Provide Procreative Benefits for Service-Connected Disabled Veterans.

Additional questions submitted by Honorable Chris Smith of New Jersey

Answers submitted by
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1. The language in HR 3161 excludes procreative services for veterans which are "not reasonably necessary to overcome the effects of veterans' service-connected disability." In your opinion, exactly what is "reasonably necessary procreative treatment" for disabled veterans?

Answer: Congressman Smith, you raise an important question that is difficult to answer. Exactly what constitutes "reasonable" procreative services is a personal and subjective determination. On the one hand, an infertile couple who have tried unsuccessfully for years to have children may consider any infertility treatment "reasonable." Because of their great desire to have children, these couples may may undergo any new or potential therapeutic procedures in their quest to procreate. On the other hand, some religious groups, such as the Roman Catholic Church, find that certain infertility treatments like in vitro fertilization and embryo transfer are "unreasonable." This determination is based on moral and religious grounds.

2. What is the rate of failure for embryo transfer?

Answer: At the present time, Congressman Smith, there is very little data available to answer your question accurately and with certainty. However, from our ongoing assessment, we would estimate the failure rate to be high, perhaps 50 to 70 percent.

3. How many embryos conceived by in vitro fertilization, in a culture dish, are discarded rather than used for embryo transfer?

Answer: Congressman Smith, there is no comprehensive data available on the number of embryos discarded by in vitro fertilization programs. However, from our own study we would estimated this number to be relatively low for the following reasons: 1) a number of IVF programs have adopted the policy that they fertilize only the number of eggs that they are willing to transfer during a given cycle. That is, no extra embryos are created. 2) Perhaps more important, there has been the increasing use of cryopreservation techniques, embryo freezing, which allow the infertility professional to freeze any extra embryos that had resulted. These embryo could then be used at a later date.

4. What is embryo flushing?

Answer: Embryo flushing, also known as ovum-transfer, uterine lavage or flushing, is a procedure that involves the retrieval of an embryo from the uterus by means of a specially designed catheter. After carefully monitoring a menstrual cycle to determine the point of ovulation, artificial insemination is performed on a fertile donor woman. Several days later a specially designed catheter is used to literally "flush" the embryo out of the donor's reproductive tract. The retrieved embryo is them transferred to a waiting recipient whose cycle has been synchronized in such a way that the uterine lining is prepared for implantation to occur.

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